



URGENT FIELD SAFETY NOTICE

June 14, 2024

Dear Valued McKesson Customer:

Smiths Medical has notified McKesson Medical-Surgical Inc. (MMS) of an Urgent Medical Device Notice regarding specific lot(s) of their Various Tracheostomy Tubes. This notice has been issued because the securement flange of the product may tear due to a manufacturing defect. If the flange on the item is torn or broken, the tracheostomy tube may not stay in position in the trachea. This can lead to tracheostomy displacement or decannulation. Either event may result in an inability to properly ventilate or protect the airway. Either can contribute to a catastrophic adverse event. To date, Smiths Medical has received thirty-five (35) reports of serious injury and one (1) death associated with this issue. Affected product first shipped June 18, 2019.

This Urgent Field Safety Notice is being done with the knowledge of the U.S. Food and Drug Administration. McKesson Medical-Surgical Inc. has taken appropriate action per this notice.

For clinical inquiries, please contact Smiths Medical at **(800) 258-5361**.

A review of our records indicates that your company may have purchased items included in this notification. Carefully review the information in this letter and follow the instructions provided below.

Refer to Attachment 1 for a list of affected item(s) and lot number(s) distributed by McKesson Medical-Surgical

McKesson Customer Instructions:

- 1.) Immediately discontinue use of any product matching the affected item(s) and lot number(s) listed in Attachment 1. If you have no products matching the affected item(s) and lot number(s), no further action is needed.
- 2.) A copy of the Urgent Medical Device Notification from Smiths Medical has been included for reference.
- 3.) If you have product affected by this notice, contact Sedgwick at **1-888-628-0731** or via email at smithsmedical3513@sedgwick.com to obtain a response form. Please indicate you are a McKesson Medical Surgical Customer when requesting the form.
- 4.) If you have product affected by this notice and have not requested replacement product from Sedgwick, fill out the McKesson Reply Form and return it to our Corporate Customer Service Center via email at MMSRecalls@McKesson.com or fax at **(866) 871-0270**. To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.
 - **Please note: Your submitted McKesson Reply Form must include the Reference ID # provided by Sedgwick.**
 - **Please place a new order for replacement product if there is an immediate need.**
- 5.) Please dispose of any affected product in your possession in accordance with your institution's policies and procedures.
- 6.) If you have further distributed any of the item(s) referenced in this notification, provide your accounts with a copy of this Field Safety Notice.

McKesson Medical-Surgical Inc.

We sincerely apologize for any inconvenience this notice may have caused you and your staff. If you have any questions about information provided in this communication, please contact our **McKesson Medical-Surgical Recall Message Center** at MMSRecalls@McKesson.com or call **(800) 688-8840**.

Thank you for your prompt attention,

McKesson Medical-Surgical Inc.

ATTACHMENT 1



MMS #	MFG Catalog #	Description	Affected Lot(s)				
368142	60PFS35	TUBE, FLEXTEND TRACH PED 3.5MM60PF35	3840084	3946229	4056230	4179357	4331613
			3843107	3946230	4060212	4185420	4331614
			3853456	3946231	4060213	4196279	4335008
			3853457	3955802	4063185	4197615	4335009
			3853458	3962598	4071981	4201384	4335010
			3858172	3962599	4075241	4204817	4335011
			3868320	3982672	4083914	4206819	4345012
			3874291	3988094	4089301	4209565	4352785
			3874292	3988096	4092633	4216323	4352786
			3874293	3988097	4097833	4217444	4360406
			3874294	3991159	4105259	4218707	4360407
			3880702	3991160	4107594	4221345	4360408
			3884241	3991161	4110454	4223730	4369598
			3887745	3991162	4116094	4231501	4374441
			3891532	4005654	4122438	4233963	4374443
			3901293	4008218	4128018	4233964	4381018
			3904667	4008219	4130990	4240150	4381019
			3907987	4015546	4134027	4254247	4381020
			3920937	4015547	4145710	4260068	4383627
			3920938	4021418	4148001	4273426	4383628
			3930041	4026694	4151036	4279333	4383632
			3936575	4033724	4153618	4283240	4388169
			3942465	4035743	4159944	4286802	4388170
			3942466	4048010	4163822	4289480	4388171
			3942467	4051625	4163823	4292167	4388172
			3942468	4053720	4176221	4292168	4393410
					3946228		
			368143	60PFS40	TUBE, FLEXTEND TRACH PED 4.0MM60PF40	3835740	3959304
3868304	3959305	4063186				4206820	4335013
3868305	3962576	4063187				4209566	4335014
3868306	3982674	4071985				4209567	4345013
3868307	3982679	4071986				4212780	4345014
3868309	3982680	4075242				4216324	4348476
3868310	3982683	4077110				4218708	4348477
3868311	3988100	4080791				4221346	4351240
3871061	3988101	4089309				4231502	4355431
3880721	3988102	4093736				4233965	4355432
3880722	3991164	4107572				4233967	4357235
3884259	3991165	4107573				4234639	4357236
3887731	3991168	4113115				4237385	4357237
3894886	4005655	4119101				4240151	4358510
3894887	4005656	4122448				4254248	4365777
3897887	4005662	4128031				4260069	4369600
3901308	4005664	4139013				4273427	4379960

MMS #	MFG Catalog #	Description	Affected Lot(s)				
368143	60PFS40	TUBE, FLEXTEND TRACH PED 4.0MM60PF40	3907996	4005665	4153596	4279334	4381021
			3907997	4005666	4159975	4283241	4383629
			3918003	4015548	4161991	4286803	4383630
			3920955	4015549	4163834	4286804	4383631
			3942504	4015550	4171552	4289481	4388173
			3942505	4033725	4176239	4289482	4388174
			3946268	4048022	4179358	4292169	4388175
			3946269	4051650	4180464	4292170	4389901
			3955783	4051651	4185421	4322675	4389902
			3955784	4053718	4185422	4331615	4399188
368144	60PFS45	TUBE, FLEXTEND TRACH PED 4.5MM60PF45	3955785	4056236	4185423		
			3843109	3988103	4083912	4216325	4347208
			3853462	3991169	4093737	4217445	4351241
			3868224	3991170	4105258	4223731	4353064
			3871045	3991171	4107600	4231504	4353095
			3877666	3991172	4113105	4237386	4374444
			3884240	4015552	4122436	4240152	4374445
			3887744	4015553	4136141	4254249	4374446
			3894868	4015556	4148002	4276466	4379941
			3901292	4015557	4156616	4279335	4381022
			3907986	4018520	4163820	4289483	4383633
			3923717	4033726	4179359	4289484	4383634
			3939634	4035745	4185424	4292172	4388176
			3942458	4051624	4196280	4322676	4388177
			3942460	4053731	4197617	4335015	4388179
			3949039	4060211	4209568	4335016	4389903
			3955800	4071980	4212781	4345015	4395789
3982682							
368145	67N035	TUBE, TRACH TTS NEO 3.5MM	3923736	3955773	4016046	4344968	4383593
			3952406	3965335	4334879	4351233	4395736
368146	67P035	TUBE, TRACH TTS PED 3.5MM	3853387	3981978	4100887	4180451	4334885
			3874306	3997797	4119100	4213400	4334886
			3880716	4011359	4128030	4221332	4362876
			3894885	4012663	4136120	4240124	4362877
			3907998	4026682	4145720	4273414	4362878
			3931149	4051652	4148011	4279319	4369529
			3939662	4080789	4153597	4292153	4380069
			3942508	4086022	4156651	4327931	4395746
			3942509	4095912	4168178	4331561	4399129
			3981976				
368147	67P040	TUBE, TRACH TTS PED 4.0MM	3853388	3981977	4097825	4273415	4358512
			3880696	4005579	4110433	4276446	4358514
			3901312	4011360	4122425	4286790	4362884
			3918020	4033702	4136121	4292155	4365801
			3926977	4051617	4145676	4327926	4369541
			3936572	4056238	4159986	4331562	4383598

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MMS #	MFG Catalog #	Description	Affected Lot(s)				
368147	67P040	TUBE, TRACH TTS PED 4.0MM	3942448	4060202	4161956	4334888	4388105
			3946287	4077065	4207455	4344973	4393389
			3955806	4083937	4216304	4352762	4399130
			3965921	4086033	4221333	4353077	4400627
368148	67P045	TUBE, TRACH TTS PED 4.5MM	3853389	3946276	4091402	4234642	4348413
			3853390	3955778	4107574	4240125	4353069
			3874307	3981983	4122449	4260054	4369547
			3880718	3997799	4131003	4273416	4369549
			3887718	3997800	4151016	4276447	4369551
			3897880	4015527	4159971	4279320	4369553
			3923734	4015528	4180452	4328211	4369554
			3939663	4035692	4213401	4331563	4380070
			3939664	4051653	4216302	4334889	4399131
			3945817	4063165	4218695	4334890	4400628
			3946275	4077112	4221334		
			368149	67P050	TUBE, TRACH TTS PED 5.0MM	3802119	3942464
3853391	3949036	4053732				4168157	4331566
3853392	3949037	4060210				4171574	4344975
3874290	3949038	4077095				4179340	4352766
3887747	3959337	4083915				4197604	4353078
3891533	3965923	4086008				4217432	4369531
3894867	3981979	4107595				4237352	4383599
3901290	3991126	4116096				4273417	4388106
3904665	4005585	4128019				4292156	4388107
3917980	4009522	4142417				4322656	4389871
3923719	4018498	4153616				4328212	4395747
3923720	4033703	4156614				4331564	4399132
368150	67P055	TUBE, TRACH TTS PED 5.5MM	3802119	3894896	4008199	4119120	4327919
			3853391	3897852	4018499	4130986	4331567
			3853392	3907994	4018500	4136122	4334893
			3874290	3918007	4035693	4142454	4334894
			3887747	3926983	4048017	4151009	4344337
			3891533	3936569	4051630	4156649	4351223
			3894867	3939661	4056240	4159970	4352767
			3901290	3942457	4063167	4161989	4374406
			3904665	3949050	4071111	4171575	4374407
			3917980	3955819	4077082	4185406	4380071
			3923719	3962602	4083941	4207454	4380072
			3923720	3981980	4085996	4213402	4380073
			3853393	3987939	4092638	4233738	4383600
			3868203	3987940	4096831	4237353	4388108
			3868205	3997801	4105246	4286792	4388109
			3880703	4001126	4107570	4322657	4388110
3887738	4005586	4116086	4327918	4393390			

MMS #	MFG Catalog #	Description	Affected Lot(s)				
408489	60PFS25	TUBE, FLEXTEND TRACH PED 2.5MM60PF25	3868288	3942491	3988093	4075235	4335004
			3901288	3952376	4015545	4086043	4348474
			3917984				
408490	60PFS30	TUBE, FLEXTEND TRACH PED 3.0MM60PF30	3853454	3991157	4092648	4185419	4351239
			3868300	4005649	4097834	4201383	4374438
			3871052	4005650	4110453	4206818	4374439
			3884251	4018519	4119110	4216322	4374440
			3907992	4029510	4131005	4221344	4383626
			3939630	4035742	4136139	4273425	4388167
			3952417	4048015	4148028	4276465	4388168
			3955789	4051632	4159992	4283239	4389899
			3962601	4066295	4171551	4292166	4393409
			3965922	4077078	4176201	4335005	4399180
			3982669	4080801	4180492	4345011	4400668
			3982670				
			408491	60PFS50	TUBE, FLEXTEND TRACH PED 5.0MM60PF50	3840085	3955788
3868297	3962600	4083931				4217446	4365778
3868298	3988108	4096826				4218709	4366203
3868299	3988109	4100896				4221347	4369601
3877642	3988110	4110455				4233968	4369602
3884250	3991174	4122443				4254252	4374447
3894889	3991175	4128043				4283243	4374448
3897872	3991176	4145694				4286805	4381023
3911431	3997817	4153587				4289485	4383635
3920969	3997828	4159976				4292173	4388180
3939629	4015558	4168142				4335017	4388181
3942455	4029511	4171553				4335018	4389904
3946245	4051631	4204819				4345016	4395790
3949028	4060227	4206821				4345017	4399191
3955787							
408492	60PFS55	TUBE, FLEXTEND TRACH PED 5.5MM60PF55	3853464	3930037	3997829	4148016	4335020
			3868209	3936573	4033727	4163837	4335021
			3877656	3950394	4035746	4179360	4352789
			3877657	3982685	4053735	4180173	4362868
			3884235	3988111	4063188	4204820	4369603
			3901309	3988112	4083938	4209569	4369604
			3911422	3991177	4105250	4233969	4374449
			3930034	3991178	4110456	4276467	4383636
			3930035	3991179	4122426	4283244	4388182
			3930036	3997818	4128035	4289486	4399192
446579	60N030	TUBE, TRACH NEO SZ3.0	3853477	3955770	4089297	4204824	4335053
			3868292	3965339	4110464	4206834	4348776
			3877665	3965340	4128036	4212788	4353055
			3884248	4006289	4138992	4233976	4358515
			3904659	4051641	4159934	4254268	4381032
			3949025	4066298	4171560	4286813	4388201
			3952381	4080798	4196292	4331629	4389921

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MMS #	MFG Catalog #	Description	Affected Lot(s)				
446580	60N025	TUBE, TRACH NEO SZ2.5	3853476	3991202	4125826	4238779	4348774
			3868313	4006287	4148013	4331627	4383653
			3911441	4006294	4206833	4345039	4400691
			3965318	4097838			
446581	60N035	TUBE, TRACH NEO SZ3.5	3880712	4023792	4107578	4180455	4335054
			3904683	4048023	4119113	4212789	4348749
			3911437	4056228	4136144	4237394	4348780
			3946267	4077083	4151019	4260075	4348781
			3949046	4086032	4161994	4279346	4388202
			3952351	4096829	4171561	4331630	4389922
			4006291				
446582	60N040	TUBE, TRACH NEO SZ4	3868302	3962603	4089296	4156652	4233978
			3884255	3982698	4107569	4176206	4286814
			3907990	3988169	4128033	4209580	4345040
			3949023	4015574	4142419	4221355	4362872
			3952346	4051633			
446583	60P035	TUBE, TRACH PED SZ3.5	3840043	3952391	4095918	4212790	4331633
			3853480	3959310	4105252	4218715	4331634
			3853481	3962581	4110466	4221356	4335058
			3864261	3982700	4116092	4223739	4335060
			3871069	3982701	4128015	4231518	4335061
			3877659	3988152	4134012	4237395	4352799
			3880688	3997822	4134013	4240163	4369613
			3884267	4001216	4136146	4247295	4369615
			3891529	4005677	4139018	4254273	4374472
			3901310	4008229	4147997	4260076	4374473
			3904656	4008230	4151027	4273439	4380056
			3911424	4011385	4156605	4276479	4381033
			3920956	4015577	4163852	4283252	4382712
			3930014	4026684	4176208	4283253	4388204
			3939675	4034945	4179368	4286816	4388206
			3942522	4034948	4196294	4292179	4389925
			3952388	4077086	4201394	4322686	4393424
3952389	4083939	4206836	4327946	4395802			
3952390	4085993	4209582					
446584	60P040	TUBE, TRACH PED SZ4	3840052	3962570	4086016	4201395	4335062
			3853482	3962571	4086017	4206837	4335064
			3861126	3962572	4095923	4209583	4335065
			3868273	3982702	4107611	4217451	4335066
			3868274	3988153	4110467	4218716	4351249
			3880711	3991204	4113113	4218717	4351250
			3884254	4001217	4119089	4221357	4369616
			3894882	4005678	4122444	4226269	4369617
			3894883	4011386	4128026	4233979	4374474
3904676	4015578	4130997	4237396	4374475			

MMS #	MFG Catalog #	Description	Affected Lot(s)				
446584	60P040	TUBE, TRACH PED SZ4	3904677	4015580	4138995	4254275	4381034
			3911434	4029515	4142426	4254277	4382706
			3923724	4035761	4148005	4273440	4382707
			3933477	4035762	4153577	4276480	4382708
			3939646	4035763	4156635	4279347	4382713
			3942486	4051642	4161984	4283254	4382715
			3946253	4051643	4168172	4286817	4383655
			3949021	4053701	4179369	4289497	4388205
			3952360	4077099	4180501	4292180	4388207
			3952361	4077100	4195806	4322687	4393425
			3952362	4082681	4196293	4327944	
446585	60P045	TUBE, TRACH PED SZ 4.5	3952377	4029516	4130978	4212791	4331635
			3952378	4035764	4138991	4216334	4331636
			3952379	4051639	4142422	4221358	4335068
			3952380	4051640	4145691	4226270	4335069
			3955769	4053716	4151044	4231519	4352800
			3982703	4060205	4153613	4237397	4352801
			3982704	4071970	4159933	4240165	4352802
			3982705	4077069	4168139	4240166	4357224
			3988155	4077070	4176217	4254278	4357226
			3988156	4083907	4180500	4260077	4374476
			3988157	4086002	4185433	4260078	4374477
			4001218	4086003	4195807	4273441	4374478
			4008231	4092626	4196295	4276481	4381035
			4015582	4096837	4197626	4283256	4382714
			4018526	4107598	4201396	4286818	4383656
			4018527	4110468	4206839	4289498	4388208
			4023793	4119117	4206840	4292181	4388209
			4026673	4125816	4209584	4322688	4389927
446588	60P055	TUBE, TRACH PED SZ5.5	3853487	3982710	4083916	4206844	4327942
			3853488	3988162	4091395	4209587	4335075
			3868223	3988163	4105255	4212792	4335076
			3880715	3991206	4107591	4216336	4335077
			3897864	4005683	4113096	4223740	4351252
			3908004	4005684	4122455	4233981	4352803
			3908005	4015588	4130992	4254281	4374481
			3923725	4015590	4142434	4254282	4374482
			3936576	4015591	4145699	4254283	4380060
			3939631	4015592	4153620	4273443	4381037
			3942495	4048027	4159968	4276483	4382716
			3949031	4051649	4168153	4279349	4383658
			3952372	4053708	4173736	4283259	4388212
			3952373	4066296	4180465	4289499	4388213
			3952374	4071976	4185434	4292183	4389929
			3955790	4077092	4201397	4322690	4393427
			3982709	4080784	4204826	4327941	4399217

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MMS #	MFG Catalog #	Description	Affected Lot(s)				
468383	670180	TUBE, TRACH TTS CUFFED ADLT 8.0MM	3782496	3917892	4051684	4153650	4267579
			3794163	3920900	4056254	4156709	4276389
			3797111	3920903	4063108	4160013	4279294
			3797123	3920905	4067213	4160015	4279295
			3801405	3935873	4067214	4163879	4280800
			3801406	3939395	4067215	4168117	4283183
			3801407	3940033	4071070	4173692	4297027
			3801412	3946135	4071074	4173693	4297028
			3801413	3946139	4077140	4176347	4297030
			3801423	3946142	4083958	4176348	4299844
			3801429	3946145	4086073	4178827	4308122
			3828135	3946149	4089228	4185495	4321558
			3831758	3946150	4089229	4187480	4321559
			3831761	3952258	4089231	4196308	4321561
			3845036	3952259	4089234	4197658	4321564
			3869825	3952260	4095954	4197659	4331669
			3869827	3952261	4095955	4205250	4331670
			3869828	3984928	4105275	4205251	4335530
			3869834	3991256	4105276	4216357	4335531
			3869835	4002251	4105277	4216359	4346828
			3869836	4002258	4111667	4216361	4357767
			3890268	4002261	4113176	4218787	4358883
			3890303	4002264	4116140	4221384	4358884
			3890306	4002276	4116141	4223750	4358886
			3890308	4005760	4116143	4226281	4358887
			3894721	4005761	4119149	4229361	4370604
			3897755	4005762	4119150	4231605	4370605
			3901173	4021433	4122510	4231606	4371681
			3901174	4021434	4122511	4233995	4371683
			3901175	4021435	4125924	4240189	4371684
			3901178	4026722	4125925	4242055	4373548
			3901181	4026724	4128063	4254434	4373552
			3904526	4033784	4128064	4257854	4381792
			3904532	4033786	4131045	4257855	4381793
			3907885	4035849	4131046	4257857	4381795
			3907900	4035850	4136171	4263224	4381796
			3907902	4035851	4139051	4263226	4381797
			3907905	4035854	4139054	4265146	4393381
			3914495	4035855	4142498	4265147	4394645
			3914498	4039107	4142499	4265148	4396612
3914501	4039910	4145762	4265150	4396613			
468385	750160	TUBE, TRACH MID-RANGE AIRE-CUFF 6.0MM	3790021	3901189	4021436	4131096	4216365
			3800590	3904496	4023799	4136212	4229363
			3801381	3907895	4029461	4142486	4229364
			3827984	3939484	4035831	4145818	4257858
			3827985	3939485	4042010	4156756	4263227

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MMS #	MFG Catalog #	Description	Affected Lot(s)				
468385	750160	TUBE, TRACH MID-RANGE AIRE-CUFF 6.0MM	3827986	3948992	4048004	4168094	4276390
			3839579	3959207	4054475	4176332	4335536
			3845047	3962464	4077142	4191370	4362636
			3889987	3984937	4089240	4192838	4371677
			3889989	3988245	4101026	4192839	4390912
			3889990	3988246	4112458	4192840	4391730
			3889991	4002287	4122498	4197660	4391731
			3889992	4015646	4128115	4205253	4401458
			3897746				
468386	750170	TUBE, TRACH MID-RANGE AIRE-CUFF 7.0MM	3801538	3870314	4008258	4131075	4192841
			3828066	3870315	4008259	4134121	4197661
			3828068	3870317	4008260	4136191	4197662
			3828071	3901072	4026720	4139082	4257859
			3839570	3942402	4033787	4145790	4263229
			3845070	3952277	4067208	4148043	4331671
			3849724	3962454	4096871	4151104	4363783
			3852697	3988247	4101024	4171675	4366576
			3870312	3991258	4117748	4173694	4376167
3870313	4005726	4128080	4185497	4393384			
468387	750180	TUBE, TRACH MID-RANGE AIRE-CUFF 8.0MM	3801535	3952216	4107661	4192842	4331672
			3801537	3959218	4110491	4192843	4335537
			3827978	4002284	4119152	4201737	4346834
			3827980	4005749	4125917	4229366	4371674
			3839573	4005750	4136209	4233997	4371675
			3839574	4021439	4139048	4242056	4391733
			3839575	4046816	4168109	4255460	4393385
			3870214	4077143	4180539	4291924	4393386
			3870216	4097852	4185498	4293044	4401163
3901032	4105325						
484460	67N040	TUBE, TRACH NEO 4.0	3877658	3923737	3936563	3942521	4016051
493829	60P025	TUBE, TRACH UNCUFF PED SZ2.5 (1/BX)	3901307	4015575	4110465	4226268	4374469
			3955786	4035758	4156650	4254269	4389923
			3991203	4083928	4176238	4331631	
493830	60P030	TUBE, TRACH UNCUFF PED 3.0MM (1/BX)	3853478	3952366	4040757	4206835	4331632
			3868293	3959293	4086004	4216332	4335057
			3868294	3982699	4092627	4217450	4374470
			3897861	3997821	4136145	4223738	4374471
			3904660	4001215	4145692	4254270	4382705
			3926961	4011384	4159935	4273438	4388203
			3936578	4015576	4185432	4276478	4389924
			3952364	4024940	4201393	4286815	4399210
			3952365	4028385			
511325	67N025	TUBE, TRACH NEONATAL 2.5	3894899	4139007	4327887	4331545	
511326	67N030	TUBE, TRACH NEONATAL 3.0	3853378	3918002	4051629	4171571	4221331
			3868286	4029491	4128032	4185401	4348407
			3887733				

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MMS #	MFG Catalog #	Description	Affected Lot(s)				
513858	65N030	TUBE, TRACH CUFFED NEONATAL SZ3	4334858				
535918	65P040	TUBE, TRACH CUFF PED 4.0MM	3868319	3887746	3904668	4289465	4374395
535919	65P045	TUBE, TRACH CUFF PED 4.5MM	4204801	4216296			
535920	65P050	TUBE, TRACH CUFF PED 5.0MM	3868226	3942493	4110429	4221325	4369532
			3871030	3955805	4139011	4289466	4369533
			3871031	4015525	4163824	4328204	4388090
			3930040	4092637	4179335		
535921	65P055	TUBE, TRACH CUFF PED 5.5MM	3840082	3959335	4100882	4159942	4334869
			3871044	4011352	4107599	4173721	4351229
			3901291	4035681	4119123	4195801	4351230
			3926980	4056231	4134024	4213395	4353075
			3942462	4077094	4138988	4218688	4389862
			3942463	4083913	4153615	4267837	4400621
			3952341				
543687	65P030	TUBE, TRACH BIVONA CUFFED PED 3.0	3923718	3930042	4221324	4331542	
543688	65P035	TUBE, TRACH BIVONA CUFFED PED 3.5	3942487	4331543	4369540		
543689	65N025	TUBE, TRACH BIVONA CUFFED NEONATAL 2.5	4334857				
543690	65N035	TUBE, TRACH BIVONA CUFFED NEONATAL 3.5	4204800				
543691	65N040	TUBE, TRACH BIVONA CUFFED NEONATAL 4.0	4221322				
543692	67P025	TUBE, TRACH BIVONA CUFFED TTS PED 2.5	3880708	3942483			
543693	67P030	TUBE, TRACH BIVONA CUFFED TTS PED 3.0	3853386	3926964	4080781	4168144	4374404
			3871064	3939647	4089294	4218694	4374405
			3880713	3946264	4110432	4279318	4383597
			3891523	3949043	4125827	4334884	4388104
			3901304	4015526	4150020	4344971	4395745
580731	60NFP40	TUBE, TRACH SIL 4.0MM+	3840062	3959302	3991144	4212772	4374429
			3877647	3982646	4008210	4322674	4388156
			3891522	3982652	4015521	4347201	4389892
			3904684	3991143	4107579	4369591	4399164
			3931151				
583096	60NFP35	TUBE, TRACH SIL 3.5 PED	3840087	3982647	4029505	4196271	4348459
			3853439	3982648	4033718	4209562	4351235
			3874300	3982649	4070851	4217440	4374426
			3880697	3982650	4077108	4231492	4374427
			3894865	3988078	4093729	4233960	4374428
			3917996	3991141	4122434	4240143	4383621
			3939659	3991142	4156641	4276461	4388154
			3949049	4001198	4159993	4322673	4388155
			3955818	4008208	4173730	4334985	4389891

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MMS #	MFG Catalog #	Description	Affected Lot(s)				
650073	60SP050	TUBE, TRACH BIVONA W/STR FLNG UNCUFF PED 5.0	3840086	4001223	4134017	4218726	4352805
			3868219	4015611	4145722	4233986	4369628
			3887748	4015613	4147983	4254292	4374488
			3897855	4027992	4156662	4254293	4380062
			3907970	4027993	4163817	4276488	4383663
			3942494	4040760	4179374	4279351	4388219
			3949034	4053719	4180461	4289503	4388220
			3952382	4066285	4196302	4322699	4389935
			3952383	4089299	4206849	4327950	4399222
			3988167	4100886	4209593	4335093	4400710
			3997827	4113120	4216340		
651877	60NFP30	TUBE, TRACH FLEXTEND+ NEO 3.0MM	3868231	3982651	4086006	4180468	4365774
			3877660	3988077	4093728	4204814	4369590
			3884269	4001129	4100888	4206813	4374425
			3894895	4023787	4125803	4218703	4381011
			3907972	4035728	4151031	4231491	4388152
			3917986	4043933	4156611	4233959	4388153
			3939639	4053733	4159945	4276460	4389890
			3955816	4060214	4168188	4322672	4399162
			3955817	4066286	4179353	4351234	
663123	67SP050	TUBE, TRACH CUFFED STRT FLANGEPED SZ5	3853435	3959338	4086009	4179352	4348453
			3853436	3962595	4100883	4185416	4348454
			3874295	3982061	4113099	4204812	4348455
			3891534	3997813	4125808	4213416	4353081
			3907988	4008207	4134025	4221340	4353478
			3920939	4018514	4142418	4286799	4369588
			3920940	4026695	4151038	4327922	4369589
			3926982	4028692	4156617	4328231	4388149
			3942469	4028710	4161973	4334967	4395776
			3949040	4077096	4171585	4344995	4400656
683057	60PFP45	TUBE, TRACH FLEX PLUS 4.5MM	3802254	3936581	4018518	4136138	4237381
			3853446	3939674	4029507	4139017	4247292
			3868246	3946285	4035733	4147996	4334992
			3874301	3949026	4049431	4156604	4345008
			3880687	3955771	4092628	4159996	4348461
			3891528	3955772	4093731	4168151	4358485
			3894908	3982659	4105251	4171544	4379939
			3904654	3997816	4110447	4180471	4388163
			3918008	4005641	4122423	4212775	
			3952400	4051658	4122456	4334996	
691131	60PFP55	TUBE, FLEXTEND TRACH PED 5.5MM	3868227	3959306	4056243	4134029	4347203
			3880723	3982662	4063181	4156629	4358488
			3894910	4001203	4093733	4206815	4388164
			3904680	4005644	4107592	4233962	4399172
			3952400	4051658	4122456	4334996	



MMS #	MFG Catalog #	Description	Affected Lot(s)				
714195	60SN035	TUBE, TRACH UNCUFFED 3.5MM	3871055	3997824	4122445	4221360	4345044
			3897844	4008232	4134010	4223741	4348748
			3926955	4015594	4151017	4223742	4348785
			3952357	4023794	4156658	4260079	4348786
			3952358	4033738	4168183	4276484	4381038
			3952359	4035767	4196299	4322692	4382717
			3962568	4092629	4209589	4335079	4389930
			3991208	4107577			
714196	60SN040	TUBE, TRACH UNCUFFED 4.0MM	3861128	4015601	4116093	4176211	4292184
			3868285	4026674	4125818	4212793	4348787
			3952368	4077098	4134020	4233982	4348788
			3952369	4091399	4151046	4254286	4348789
			3991209	4107593			
726160	60PFSS45	TUBE, FLEXTEND TRACH PED 4.5MM	3853473	3991196	4097836	4212785	4335046
			3853474	3991197	4105254	4216331	4335047
			3868198	3991198	4107585	4217449	4345035
			3868199	3991199	4110462	4218713	4347209
			3874305	4001213	4116091	4226267	4347210
			3880707	4001214	4122447	4231513	4352794
			3884261	4008225	4125825	4231514	4353059
			3894905	4008226	4128017	4233975	4353060
			3897859	4015570	4139001	4237393	4355429
			3904674	4015571	4145697	4240162	4355430
			3908003	4033736	4148015	4254264	4374461
			3918013	4035755	4151029	4260074	4374462
			3926960	4040577	4153609	4267857	4374463
			3930026	4048026	4159951	4267858	4379948
			3939624	4051644	4161965	4273437	4379962
			3939669	4051645	4176227	4276475	4383647
			3942482	4056242	4185429	4276476	4383648
			3946291	4060218	4196288	4279342	4383649
			3946292	4060219	4196289	4279343	4388196
			3955775	4063191	4197625	4283250	4388197
			3962573	4066293	4201390	4283251	4388198
			3982694	4071974	4206830	4286812	4389918
			3988128	4083911	4206831	4292177	4393420
			3988129	4091393	4209578	4322683	4393421
3991195	4093740	4209579	4335045				
726792	60SP045	TUBE, TRACH N/CUFF PED SZ4.5	3840064	3962575	4095915	4185439	4289502
			3853497	3982714	4105247	4197630	4335091
			3868193	3997826	4113116	4201400	4335092
			3868194	4001222	4119114	4212796	4345047
			3868196	4011387	4122452	4216339	4348796
			3887754	4015609	4130985	4217453	4362881
			3894901	4015610	4142432	4221363	4362882

MMS #	MFG Catalog #	Description	Affected Lot(s)				
726792	60SP045	TUBE, TRACH N/CUFF PED SZ4.5	3897885	4035770	4145695	4233984	4374487
			3911439	4051647	4147994	4237400	4381039
			3942488	4056253	4153601	4254291	4382711
			3948793	4066297	4161995	4260081	4383662
			3952352	4077080	4161996	4276487	4389934
			3952354	4080782	4168146	4283263	4393431
			3955808	4089290	4179373	4286826	4399221
			3959300				
796353	60PFPS50	TUBE, TRACH BIVONA N/CUFF PED SZ5	3853453	3920951	4026678	4131004	4231498
			3877645	3920952	4035738	4139006	4331609
			3884257	3952386	4053714	4148007	4335001
			3887720	3952387	4066287	4153594	4362851
			3887721	3962578	4083930	4161988	4362852
			3911440	3991155	4091404	4171548	4369595
			3914569	4005647	4107568	4196276	4393408
			3918000	4011378	4113114	4206817	4399177
			3918001	4023789	4125823		
796549	60PFPS60	TUBE, TRACH BIVONA NEO SIL 6.0AMESMI	3884265	3891525	3982667	4107588	4217443
			3887739	3897850	4005648	4122424	4231500
			3891524	3907969	4015544	4134014	4240149
			3897847	3918009	4026681	4139016	4345010
			3918016	3920953	4035741	4145701	4348471
			3923716	3942511	4041958	4168150	4374436
			3936570	3949022	4053703	4171549	4374437
			3946284	3959307	4077088	4180467	4399179
			3952336	3959308	4091410	4212779	4400667
			3952337	3959309	4105253		
815763	67SP055	TUBE, TRACH W/CUFF PED 5.5MM W/STRT NECK FLANGE	3874309	3955803	4053736	4163849	4328233
			3884258	3965906	4077081	4173729	4334968
			3887753	3982062	4091409	4185417	4344342
			3894900	3997814	4100897	4201372	4348457
			3897882	4015536	4113117	4231490	4374424
			3911438	4026669	4125828	4247291	4383620
			3926963	4026670	4136136	4289479	4388150
			3941951	4033717	4145696	4322671	4388151
			3946266	4035727	4153602	4327888	4395777
			3949044	4048019	4159989	4328232	4400657
			3939632	4016061	4204813	4334983	4348458
3942500							
816485	60NFP25	TUBE, TRACH FLEXTEND+ UNCUFF NEONATE 2.5MM	3939632	4016061	4204813	4334983	4348458
			3942500				
			3874308	3946273	4035732	4097832	4218705
			3880719	3946274	4038946	4116083	4221342
			3887716	3955779	4051654	4139002	4237380
			3887717	3962577	4056235	4153592	4334991
816486	60PFP40	TUBE, TRACH FLEXTEND+ UNCUFF LNG PED 4.0MM	3901303	3982658	4071987	4159972	4345007
			3907999	3997815	4077111	4168179	4348460



MMS #	MFG Catalog #	Description	Affected Lot(s)				
816486	60PFP40	TUBE, TRACH FLEXTEND+ UNCUFF LNG PED 4.0MM	3918005	4001202	4080792	4171543	4358483
			3918006	4015539	4091403	4176236	4383624
			3942497	4033721	4093730	4180453	4399170
816487	60PFP50	TUBE, TRACH FLEXTEND+ UNCUFF LNG PED 5.0MM	3853447	3959336	4043937	4110448	4180494
			3853448	3982660	4051623	4110449	4218706
			3868225	3982661	4060209	4122435	4254243
			3901289	3991152	4077093	4151048	4334995
			3931140	4005642	4086007	4156613	4348462
			3942461	4018517	4093732	4171545	4365775
			3952342	4029508	4105257	4176220	4366206
			3952343	4035734			
			816517	65SN040	TUBE, TRACH AIRE-CUFF STRT FLANGE NEO 4.0MM	4254207	
816518	65SP025	TUBE, TRACH AIRE-CUFF STRT FLANGE NEO 2.5MM	4221327				
816519	65SP030	TUBE, TRACH AIRE-CUFF STRT FLANGE NEO 3.0MM	4254212				
816520	65SP035	TUBE, TRACH AIRE-CUFF STRT FLANGE NEO 3.5MM	3868192	4292151	4388094		
816521	65SP040	TUBE, TRACH AIRE-CUFF STRT FLANGE NEO 4.0MM	4237345	4348397	4358513		
816522	65SP045	TUBE, TRACH AIRE-CUFF STRT FLANGE PED 4.5MM	3955777	3997788	4035685	4113119	4334874
816523	65SP050	TUBE, TRACH AIRE-CUFF STRT FLANGE PED 5.0MM	3868214	3997789	4107590	4139012	4352754
			3936579	4029490	4122453	4197603	4383592
			3952367	4034958	4134016	4351232	4399125
816524	65SP055	TUBE, TRACH AIRE-CUFF STRT FLANGE PED 5.5MM	3897865	3987925	4105263	4159977	4328207
			3952418	4005582	4113111		
816525	67SN025	TUBE, TRACH TTS CUFF STRT FLANGE NEO 2.5MM	3897849	4016050	4328223	4352775	4365802
			3936582				
816526	67SN030	TUBE, TRACH TTS CUFF STRT FLANGE NEO 3.0MM	3877644	4283236	4348425	4374420	4399158
			4122450	4331589	4353070		
816527	67SN035	TUBE, TRACH TTS CUFF STRT FLANGE NEO 3.5MM	3861151	3923739	4185413	4348429	4381009
			3887737	4016044	4237375	4348430	4388146
			3907993				
816528	67SN040	TUBE, TRACH TTS CUFF STRT FLANGE NEO 4.0MM	3861153	3961255	4110442	4180472	4334961
			3894898	4016052	4130976	4328226	4365803
			3923715				
816529	67SP025	TUBE, TRACH TTS CUFF STRT FLANGE PED 2.5MM	3904678	3961754	4161974	4334962	4352776
816530	67SP030	TUBE, TRACH TTS CUFF STRT FLANGE PED 3.0MM	3877648	3955804	4119088	4344992	4388148
			3897883	3962574	4201369	4374423	4395775
			3931152	4071972	4328228	4381010	4400654
			3942489	4075249	4331583		

MMS #	MFG Catalog #	Description	Affected Lot(s)				
816532	67SP040	TUBE, TRACH TTS CUFF STRT FLANGE PED 4.0MM	3853432	3942485	4053717	4148029	4331585
			3871054	3952370	4071971	4153614	4331586
			3880706	3952371	4075250	4159936	4334965
			3891531	3987968	4086005	4168140	4348439
			3897862	3997810	4095920	4185414	4348441
			3907985	3997811	4110443	4217439	4362885
			3920947	4021420	4125817	4221339	4365804
			3926962	4048008	4142423	4237376	4380079
816533	67SP045	TUBE, TRACH TTS CUFF STRT FLANGE PED 4.5MM	3853433	3965905	4071973	4168143	4328230
			3871065	3997812	4075251	4176203	4331587
			3877649	4011375	4086028	4185415	4334966
			3887752	4018513	4086029	4196270	4344994
			3897884	4029504	4110444	4201371	4348442
			3908002	4043932	4128011	4240140	4348443
			3917995	4051648	4139009	4273424	4353071
			3926965	4053737	4151021	4286798	4365805
			3946265	4063179	4156654	4289478	4399161
			3952356				
816617	60SN025	TUBE, TRACH UNCUFF STRT FLANGENEO 2.5MM	3853489	3955794	4066280	4327883	4353056
			3868323	4035766	4322691		
816618	60SN030	TUBE, TRACH UNCUFF STRT FLANGENEO 3.0MM	3874310	3959303	4077090	4159969	4327917
			3930032	3965337	4092647	4197627	4353057
			3946244	3965338	4110469	4209588	4383659
			3949032	4006292	4130991	4286821	4395805
			3952375	4060224			
816619	60SP025	TUBE, TRACH UNCUFF STRT FLANGEPED 2.5MM	3853490	4053702	4168173	4204827	4327884
			3894874	4091396	4179371	4216338	4345045
			3952363	4110470	4197628	4223743	4365784
			4008233	4156636			
816620	60SP030	TUBE, TRACH UNCUFF STRT FLANGEPED 3.0MM	3853491	3982711	4107575	4204828	4335085
			3853492	4001220	4116084	4206846	4345046
			3868316	4015600	4122451	4217452	4369626
			3877643	4021423	4131002	4221361	4374484
			3884256	4024939	4139003	4247296	4382718
			3894888	4051655	4142430	4254287	4388214
			3923735	4060225	4153593	4279350	4389931
			3952385	4077113	4161992	4283260	4395806
			3955780	4083929	4185437	4286823	4400704
			3965909	4086024	4196300		
816621	60SP035	TUBE, TRACH UNCUFF STRT FLANGEPED 3.5MM	3840044	3988164	4095919	4209591	4322695
			3853493	3988165	4107587	4212794	4335086
			3853494	3991210	4110471	4218724	4335087
			3868228	4005685	4119115	4226272	4335088
			3868229	4012662	4130987	4233983	4351253
			3884268	4018528	4139019	4237398	4352807



MMS #	MFG Catalog #	Description	Affected Lot(s)				
816621	60SP035	TUBE, TRACH UNCUFF STRT FLANGEPED 3.5MM	3897848	4026679	4145700	4240167	4369623
			3907968	4034946	4151028	4254288	4369624
			3911420	4034947	4156660	4260080	4369625
			3926971	4056229	4161959	4276485	4382710
			3949027	4066278	4161960	4283261	4388215
			3952407	4077085	4176210	4286824	4389932
			3952408	4083940	4197629	4289500	4393428
			3965910	4085994	4206847	4292185	4393429
		3982712					
816622	60SP040	TUBE, TRACH UNCUFF STRT FLANGEPED 4.0MM	3840061	3949042	4051661	4151024	4276486
			3853495	3952338	4056239	4153604	4283262
			3853496	3952339	4063194	4163838	4286825
			3861152	3952340	4070854	4171562	4289501
			3868210	3955796	4077066	4171563	4322696
			3868211	3955797	4083936	4176204	4327952
			3868212	3982713	4089288	4185438	4335089
			3894897	3988166	4092646	4201398	4335090
			3897846	3991211	4100889	4204829	4348790
			3907967	4001221	4107586	4206848	4352806
			3911423	4015603	4113097	4209592	4353058
			3930038	4015605	4119109	4212795	4369629
			3936574	4015606	4122427	4218725	4369630
			3946288	4015608	4130975	4221362	4374486
			3946289	4026691	4134011	4237399	4380061
			3946290	4035769	4142438	4254289	4383660
3948791	4041966	4145678	4273444	4388216			
816623	60SP055	TUBE, TRACH UNCUFF STRT FLANGEPED 5.5MM	3868322	3982716	4092632	4206851	4322700
			3901294	3988168	4110472	4209594	4327889
			3911430	3991214	4128020	4212797	4335094
			3936571	3991215	4134026	4223744	4351256
			3942470	4015615	4145711	4233985	4374489
			3948792	4015617	4161972	4276489	4374490
			3952344	4051626	4173739	4279352	4380063
			3952345	4066279	4180496	4292186	4399223
816624	65P025	TUBE, TRACH AIRE-CUF 4MM OD 38MM LNG PED	4016049	4334862			
816625	65SN025	TUBE, TRACH AIRE-CUF STRT FLANGE NEO SZ2.5	4201335				
816626	65SN030	TUBE, TRACH AIRE-CUF STRT FLANGE NEO SZ3	4267838	4399123			
816627	65SN035	TUBE, TRACH AIRE-CUF STRT FLANGE NEO SZ3.5	4221326	4348390			

MMS #	MFG Catalog #	Description	Affected Lot(s)				
817490	60PFP60	TUBE, TRACH VEE FLEXTEND PED PLUS 6.0MM	3853449	3926956	4035735	4159946	4348463
			3880705	3942473	4048020	4173734	4374433
			3887741	3982663	4056241	4179355	4374434
			3894904	3982664	4075244	4212776	4374435
			3897853	3991153	4092639	4240147	4389897
			3918010	4015523	4100894	4331605	4399173
			3920943	4026688	4113112	4334997	
842572	60PFSS35	TUBE, TRACH BIVONA FLEXTEND+ UNCUFF STRT PED 3.5MM	3840073	3959331	4075238	4196283	4289490
			3840074	3959332	4077091	4196284	4289491
			3845208	3959333	4080785	4197619	4292175
			3853467	3982687	4083909	4197620	4322679
			3853468	3982688	4083910	4197621	4322680
			3853469	3982689	4089298	4201386	4327896
			3858171	3982690	4092630	4204822	4327897
			3861148	3988114	4092631	4206824	4331616
			3864208	3988115	4093738	4206825	4331617
			3868324	3988116	4095922	4206826	4331618
			3868325	3988119	4097812	4209571	4331619
			3871034	3988120	4100877	4209572	4335029
			3874315	3991184	4100878	4209573	4335030
			3874316	3991185	4100880	4212784	4335031
			3874318	3991186	4100881	4216326	4335032
			3874319	3997831	4107596	4216327	4335033
			3874320	3997832	4107597	4216328	4335034
			3877667	4001205	4110459	4218711	4345022
			3880698	4005667	4110460	4221349	4345023
			3880699	4005668	4113100	4223734	4345024
			3894863	4008220	4113101	4231509	4345025
			3894864	4011381	4122430	4233970	4345026
			3897858	4015560	4125809	4233971	4351243
			3901284	4015561	4125810	4237387	4351245
			3901285	4015563	4128021	4237388	4352792
			3903698	4018523	4128022	4237389	4352793
			3907977	4018525	4130989	4240155	4360411
			3907978	4026693	4134022	4240157	4360412
			3907979	4029513	4136150	4254256	4360413
			3917978	4033731	4138980	4260071	4369605
			3917979	4035749	4142449	4267850	4369606
			3920968	4035750	4142450	4267851	4369607
			3926978	4041967	4145703	4267852	4369608
3939627	4041968	4147998	4273429	4374455			
3939628	4043935	4147999	4273430	4374457			
3942452	4048029	4151032	4273431	4381027			
3942453	4051627	4153611	4273432	4381028			
3942454	4051628	4156608	4276469	4381029			



MMS #	MFG Catalog #	Description	Affected Lot(s)				
842572	60PFSS35	TUBE, TRACH BIVONA FLEXTEND+ UNCUFF STRT PED 3.5MM	3946232	4053722	4159938	4276470	4383639
			3946233	4053723	4161966	4276471	4383640
			3946234	4053724	4161967	4279337	4383641
			3946235	4053725	4161969	4279338	4383642
			3946236	4060207	4163816	4279339	4388187
			3946237	4060208	4176218	4283246	4388188
			3946239	4063189	4179363	4283247	4388190
			3946240	4066281	4179364	4283248	4389908
			3950393	4066282	4180490	4286806	4389909
			3955795	4071978	4185427	4286807	4393411
			3959329	4075237	4196282	4286808	
843298	60PFPS40	TUBE, TRACH FLEXTEND+ PED 4.0MM	3853451	3942549	4053709	4153590	4283238
			3853452	3959326	4056252	4159979	4331606
			3868260	3959327	4063182	4159980	4334998
			3877673	3959328	4077077	4171546	4334999
			3884242	3991154	4080799	4180493	4348464
			3894866	4005645	4086021	4196275	4348465
			3907983	4005646	4091400	4206816	4348466
			3917997	4008216	4093734	4212777	4358482
			3920962	4015542	4096847	4221343	4365800
			3920963	4021422	4110450	4231496	4365806
			3930049	4029509	4134035	4237382	4395783
			3930050	4033723	4138976	4240148	4399175
			3942548	4035736	4151008	4254245	
			844008	60NFPS30	TUBE, TRACH NEONATAL/PED FLEXTEND+ SIL 3.0MM	3853441	3946283
3868206	3955764	4051634				4159974	4334989
3868207	3962605	4053729				4161993	4345005
3871067	3982653	4066288				4168190	4345006
3877651	3982654	4077084				4180503	4351237
3887742	3988079	4083942				4185418	4362840
3897854	4001201	4092640				4209563	4369592
3904673	4008212	4096832				4218704	4369593
3907995	4011376	4105248				4231493	4374431
3926957	4018516	4110445				4233961	4383622
3930007	4023788	4122441				4254232	4389893
3939665	4029506	4128014				4276462	4399165
3942472	4035731	4138979				4327915	4400661
3946282							
847284	60NFPS35	TUBE, TRACH NEO 3.5MM STRT FLEXTEND BIVONA	3853442	3991146	4071966	4206814	4335052
			3868200	3991147	4083934	4212774	4351238
			3871058	3991148	4083935	4217441	4352783
			3877653	3991149	4092635	4223727	4353063
			3884262	4008213	4097816	4231494	4353086
			3887743	4008214	4107610	4237379	4374432
			3894902	4011377	4119111	4240144	4381013

MMS #	MFG Catalog #	Description	Affected Lot(s)				
847284	60NFPS35	TUBE, TRACH NEO 3.5MM STRT FLEXTEND BIVONA	3911432	4015538	4138997	4260066	4381014
			3918014	4026689	4151030	4276463	4381015
			3926968	4033719	4153610	4286800	4383623
			3942534	4041969	4159953	4327936	4388158
			3952348	4051659	4168147	4327937	4388159
			3955767	4051660	4173732	4331602	4389894
			3982655	4053738	4195805	4331604	4399167
			3988081	4060203	4196273	4334990	4400664
			3988082	4063180	4204815		
854107	60NFPS40	TUBE, TRACH NEONATAL 4.0MM	3853444	3962567	4053699	4173733	4240145
			3868233	3982657	4060217	4196274	4254240
			3874303	3988089	4083917	4197613	4276464
			3887749	3988092	4091394	4204816	4286801
			3901298	3991150	4110446	4209564	4327940
			3907991	3991151	4125819	4217442	4362842
			3920946	4005639	4145717	4221341	4365799
			3939636	4008215	4153576	4231495	4399168
			3949020	4026668	4161981		
867114	60PFSS30	TUBE, TRACH BIONA FLEXTEND + UNCUFFED STD STRT 3.0MM PED	3868215	3991183	4119118	4212783	4351242
			3868216	4001204	4128037	4217447	4352791
			3868217	4011379	4130977	4218710	4374450
			3868218	4011380	4134021	4221348	4374451
			3874311	4015559	4142421	4231505	4374452
			3880720	4029512	4145693	4231506	4374453
			3887755	4033728	4151047	4254255	4381024
			3894894	4033729	4156612	4260070	4381025
			3904669	4040575	4159997	4267849	4381026
			3907971	4048009	4163851	4273428	4383637
			3917982	4053713	4171554	4283245	4388183
			3926967	4060206	4176212	4289488	4388184
			3933476	4070853	4176213	4289489	4388185
			3939635	4077071	4180497	4292174	4388186
			3942492	4077072	4185426	4322678	4389907
			3946278	4083908	4196281	4327893	4395792
			3946279	4091412	4201385	4335022	4395793
			3946280	4096836	4204821	4335024	4399193
			3962580	4105256	4206823	4345018	4399195
			3982686	4110458	4209570	4345021	4400678
3988113	4113107						
921906	67PFSS35	TUBE, TRACH PED W/FLEX TEND 3.5	3835792	3959312	4083925	4201338	4329825
			3835793	3959313	4086026	4201339	4329831
			3853413	3962594	4091405	4204806	4329836
			3853414	3965924	4091406	4212765	4334941
			3858170	3965925	4096848	4213412	4334942
			3868261	3981999	4097831	4216312	4334943



MMS #	MFG Catalog #	Description	Affected Lot(s)				
921906	67PFSS35	TUBE, TRACH PED W/FLEX TEND 3.5	3868262	3987962	4100900	4216313	4334944
			3868263	3987965	4107609	4216314	4334945
			3868264	3991134	4110439	4217437	4334946
			3868265	4005598	4116102	4218698	4334973
			3868266	4005599	4116122	4218699	4344982
			3871041	4005605	4119107	4231487	4344983
			3871042	4005606	4122428	4237362	4351224
			3874323	4008203	4125807	4237363	4351225
			3884245	4008204	4128028	4237364	4352774
			3887727	4011366	4131000	4237365	4360417
			3891518	4011367	4134036	4237366	4360418
			3891519	4018508	4134037	4237367	4365787
			3894917	4018509	4136129	4240132	4369573
			3897876	4023783	4139027	4240133	4369574
			3901297	4033710	4142442	4247286	4369575
			3911418	4033711	4142455	4254223	4374415
			3911419	4035711	4148021	4254224	4374416
			3917989	4035712	4148022	4260059	4374417
			3920964	4035713	4151058	4260060	4381002
			3923741	4041963	4151059	4267840	4381003
			3923742	4043943	4156639	4267841	4381004
			3933473	4048012	4159984	4267842	4381005
			3939641	4051666	4163841	4273420	4381006
			3939643	4051667	4163843	4276455	4383609
			3939644	4053727	4168162	4276456	4383610
			3939645	4056245	4176243	4279326	4383612
			3942545	4056246	4176244	4283224	4388132
			3942546	4066300	4176246	4283225	4388133
			3946257	4066301	4176247	4283226	4388134
			3946258	4067718	4176248	4283227	4388135
			3946259	4070846	4179345	4289470	4389880
			3946260	4075247	4195803	4289471	4389881
			3946261	4077104	4196263	4322662	4389882
			3946262	4077105	4196264	4322663	4389883
			3955809	4080787	4196265	4327911	4389884
3955810	4080788	4197606	4328219	4393397			
943871	67PFSS40	TRACHEOSTOMY, PEDIATRIC TTS F LEXTEND STRAIGHT 4.0 AMESMI	3840066	3965918	4070848	4180477	4329826
			3853416	3982004	4075248	4180478	4329832
			3853417	3982005	4077074	4195804	4329837
			3853418	3982007	4080795	4196266	4331581
			3853419	3985840	4080796	4197607	4333980
			3853420	3985841	4083918	4201340	4334215
			3853421	3987966	4086015	4212766	4334216
			3868249	3987971	4089306	4216315	4334217
			3868250	3991135	4091397	4216316	4334950

MMS #	MFG Catalog #	Description	Affected Lot(s)				
943871	67PFSS40	TRACHEOSTOMY, PEDIATRIC TTS F LEXTEND STRAIGHT 4.0 AMESMI	3868251	4005610	4097819	4216317	4334951
			3874298	4005611	4100891	4218700	4334971
			3874299	4005612	4100892	4218701	4344338
			3877664	4005614	4100893	4231488	4344339
			3880692	4008205	4107602	4233954	4344987
			3884236	4008206	4107603	4237368	4344988
			3887724	4011368	4110440	4237369	4351226
			3891537	4011370	4113103	4237371	4357251
			3891538	4015533	4116107	4240134	4357252
			3894875	4015534	4119097	4240135	4357253
			3894876	4018510	4122431	4240136	4357254
			3901281	4018511	4125812	4254225	4362845
			3901282	4021417	4128039	4254226	4362846
			3904661	4023784	4130980	4254227	4362847
			3911426	4026687	4134034	4260061	4362848
			3911427	4033713	4139026	4260062	4362849
			3923728	4033714	4142452	4267845	4365788
			3930019	4035715	4145685	4273421	4365790
			3930020	4035716	4147984	4273422	4365791
			3933474	4035717	4147986	4276457	4369576
			3939688	4040573	4147987	4276458	4369577
			3942513	4041965	4151040	4276459	4383614
			3942514	4048032	4153623	4279327	4388136
			3942515	4048033	4156626	4279328	4393399
			3946293	4051620	4159963	4283228	4393400
			3946294	4051621	4159964	4283229	4393401
			3946295	4053706	4159965	4283230	4395768
			3946297	4053707	4161976	4289472	4395769
			3955756	4056247	4163831	4289473	4395770
			3955757	4060223	4179346	4292161	4399147
			3962582	4063175	4179347	4322664	4399148
			3962583	4066289	4179348	4322665	4399149
			3962584	4070847	4179349	4327912	
950547	67PFSS55	TUBE, TRACH PEDIATRIC 5.5ML TTS	3868248	3946226	4056249	4159957	4334218
			3868283	3955766	4071967	4204810	4344341
			3868284	3982056	4080800	4212769	4351227
			3880689	3982057	4089304	4254230	4362866
			3880690	3997808	4096844	4260065	4381007
			3880691	4001128	4105260	4283235	4383619
			3897873	4005629	4119095	4289476	4388144
			3911425	4011373	4125813	4292164	4388145
			3930017	4018512	4130979	4327890	4389889
			3931146	4035725	4136134	4327923	4395774
			3939677	4041964	4145690	4329827	4399156
			3939678	4048030	4151049	4329833	4400652
			3939679	4051618			

McKesson Medical-Surgical Inc.



MMS #	MFG Catalog #	Description	Affected Lot(s)				
995047	60NFPS25	TUBE, TRACH UNCUFFED NEONATAL FLEXTEND PLUS 2.5MM	3923733	3991145	4095917	4327881	4374430
			3952384	4015537	4119108	4334986	4395780
			3965919	4035730	4179354	4351236	
995062	60PFSS25	TUBE, TRACH UNCUFFED PEDIATRICFLEXTEND 2.5MM	3868303	3997819	4148027	4223732	4352790
			3894869	4038948	4163850	4234640	4362855
			3949045	4075236	4185425	4327882	4389906
			3991182	4086044			
995065	60PFSS40	TUBE, TRACH UNCUFFED PEDIATRICSTD STRT 4.0MM	3853472	3988126	4097814	4206829	4331623
			3868235	3988127	4100884	4209574	4335040
			3868236	3991189	4100885	4209575	4335041
			3868237	3991190	4107612	4209576	4335042
			3868238	3991191	4107613	4209577	4335043
			3868239	3991192	4110461	4216329	4335044
			3868241	3991193	4113109	4216330	4345028
			3868242	3991194	4113110	4218712	4345029
			3868243	3997833	4116104	4223735	4345030
			3871051	4001208	4119086	4223736	4345031
			3880704	4001210	4119087	4231510	4345032
			3884253	4001211	4125820	4231511	4345033
			3887750	4005672	4128024	4233972	4345034
			3887751	4008222	4128025	4233973	4348478
			3891514	4008223	4130995	4234637	4348479
			3891515	4008224	4130996	4234638	4348480
			3894870	4011382	4134030	4237390	4357238
			3894871	4015564	4134031	4237392	4357239
			3894872	4015565	4136149	4240160	4357240
			3894873	4015567	4138993	4254261	4357241
			3897870	4015568	4142424	4254262	4357242
			3897871	4015569	4142425	4260072	4357243
			3901300	4033732	4145715	4260073	4358509
			3903699	4033733	4148004	4267853	4365780
			3917983	4035753	4151054	4267854	4369609
			3920944	4035754	4153575	4267855	4369611
			3920945	4040576	4156631	4267856	4374458
			3926959	4041970	4159949	4273433	4374460
			3939638	4041971	4161979	4273436	4379946
			3942475	4048014	4163826	4276472	4379953
			3942476	4051635	4168165	4276473	4379954
			3942477	4053697	4168167	4276474	4383643
			3942478	4053698	4171556	4279340	4383644
3942479	4056232	4176224	4279341	4383645			
3942480	4056233	4179365	4283249	4383646			
3942481	4060215	4180450	4286811	4388192			
3946247	4060216	4185428	4289492	4388193			
3946249	4063190	4196285	4289493	4388194			

MMS #	MFG Catalog #	Description	Affected Lot(s)				
995065	60PFSS40	TUBE, TRACH UNCUFFED PEDIATRICSTD STRT 4.0MM	3946250	4066283	4196286	4289494	4389913
			3946251	4066284	4196287	4292176	4389914
			3959297	4071982	4197622	4322681	4389915
			3959298	4071983	4197623	4322682	4389916
			3988121	4075239	4201387	4327900	4389917
			3988122	4075240	4201388	4327901	4393418
			3988123	4089303	4204823	4327934	4393419
			3988124	4092636	4206827	4331622	4399203
			3988125	4093739	4206828		
995067	60PFSS50	TUBE, TRACH PEDIATRIC FLEXTENDSTANDARD STRAIGHT 5.0MM	3840057	3946242	4051656	4185430	4327905
			3868220	3946243	4053710	4196290	4335048
			3868221	3949030	4071975	4201391	4335049
			3868222	3982696	4083923	4206832	4345036
			3880714	3991200	4086011	4212786	4345038
			3884270	3991201	4097837	4218714	4351247
			3894907	4008227	4110463	4223737	4365781
			3897868	4011383	4122454	4231516	4365782
			3904679	4015572	4128023	4254266	4365783
			3911436	4023791	4139014	4267859	4383650
			3918023	4026696	4145698	4276477	4383651
			3920950	4033737	4156619	4279344	4389919
			3930029	4035756	4161975	4289495	4393422
			3930030	4043934	4168152	4322684	4393423
3946241							
995080	60PFSS55	TUBE, TRACH PEDIATRIC FLEXTENDSTD STRT 5.5MM	3868230	3946277	4085995	4171558	4335050
			3871032	3982697	4091411	4180466	4345037
			3880678	3997820	4107589	4196291	4351248
			3887732	4008228	4116089	4201392	4352796
			3894906	4015573	4125802	4212787	4374465
			3904653	4021424	4128013	4231517	4383652
			3911421	4026680	4134015	4279345	4388199
			3920954	4035757	4142436	4292178	4388200
			3923729	4051657	4151026	4322685	4389920
			3930009	4063192	4156661	4327891	4399207
			3930010	4077087	4161961	4327907	4400689
3930011							
995083	67NFP25	TUBE, TRACH NEONATAL 2.5 TTS FLEXTEND V FLANGE	3936586	4033699	4091401	4334881	
995084	67NFP30	TUBE, TRACH NEONATAL 3.0 TTS FLEXTEND V FLANGE	3874314	3955792	4011356	4116100	4331551
			3884252	3962588	4033700	4145705	4334882
			3930043	3997790	4063161	4163839	4374402
995087	67NFP35	TUBE, TRACH NEONATAL 3.5 TTS FLEXTEND VS FLANGE	3853380	3959334	4110430	4237346	4383594
			3874302	4001123	4151052	4331592	4388098
			3939680	4021415	4176229	4357246	4395737
			3952399	4086018	4218691		

McKesson Medical-Surgical Inc.



MMS #	MFG Catalog #	Description	Affected Lot(s)				
995090	67NFP40	TUBE, TRACH NEONATAL 4.0 TTS FLEXTEND V	3853381	3987930	4083924	4156634	4334883
			3952393	4033701	4122439	4237348	
995094	67PFS30	TUBE, TRACH PEDIATRIC 3.0 TTS FLEXTEND V NECK	3853403	3959311	4107582	4180479	4348419
			3874324	4060198	4116088	4213407	4380074
			3884244	4083906	4138998	4328215	4388119
			3907973	4091413	4145680	4334909	4395755
			3930052	4105249			
995095	67PFS35	TUBE, TRACH PEDIATRIC 3.5 TTS FLEXTEND V NECK	3853405	3959318	4051671	4145702	4328216
			3868268	3959319	4053726	4153579	4334912
			3871039	3981991	4060196	4161986	4334915
			3877670	3981992	4077102	4173727	4352772
			3887715	3997804	4083926	4180483	4365786
			3897877	4005592	4089293	4213408	4369563
			3914571	4015530	4095927	4217433	4383606
			3923745	4018503	4110435	4221336	4388120
			3936566	4026671	4119103	4237359	4389875
			3939652	4033708	4125804	4260057	4393393
			3942529	4041961	4136125	4279323	4399138
995097	67PFS40	TUBE, TRACH PEDIATRIC 4.0 TTS FLEXTEND V NECK	3835787	3936583	4033709	4142427	4283222
			3853406	3939681	4035707	4145681	4328217
			3864263	3942528	4043938	4151010	4331573
			3864264	3952397	4051619	4156606	4334920
			3877654	3952398	4056251	4161963	4344978
			3884237	3959325	4060221	4171578	4357248
			3894877	3962585	4080783	4213409	4362850
			3901287	3981993	4086001	4221337	4369572
			3918018	3997805	4100895	4237360	4388122
			3920960	4008201	4107581	4240130	4389876
			3930015	4015531	4119124	4254221	4395758
			3931145	4029497	4136126	4276451	4399139
			995098	67PFS45	TUBE, TRACH PEDIATRIC 4.5 TTS FLEXTEND V NECK	3861137	3962590
3868253	3981994	4077101				4142451	4334921
3880679	3991132	4083932				4151051	4344979
3887722	3997806	4089305				4161982	4355426
3887723	4005593	4092641				4171579	4380075
3904686	4018504	4097828				4179342	4388123
3923731	4029498	4100890				4237361	4389877
3936584	4041962	4119096				4260058	4395761
3942523	4051665	4122440				4276452	4399140
3952394	4060195						
995099	67PFS50	TUBE, TRACH PEDIATRIC 5.0 TTS FLEXTEND V NECK	3868275	3939676	4011364	4110436	4286795
			3868276	3942518	4018505	4116105	4322659
			3874297	3942519	4029499	4128042	4329838
			3880681	3952392	4035708	4136132	4334220

MMS #	MFG Catalog #	Description	Affected Lot(s)				
995099	67PFS50	TUBE, TRACH PEDIATRIC 5.0 TTS FLEXTEND V NECK	3894878	3959323	4053704	4145688	4362864
			3897867	3962589	4063171	4159962	4388124
			3918019	3981995	4077073	4179343	4388125
			3923726	3987958	4089307	4180474	4388126
			3930016	4005595	4097830	4213410	4393394
995100	67PFS55	TUBE, TRACH PEDIATRIC 5.5 TTS FLEXTEND V NECK	3853408	3939671	4053734	4151012	4331580
			3864260	3952349	4063172	4159955	4334931
			3871050	3965908	4077089	4163853	4352773
			3884263	3981996	4083905	4173728	4374411
			3891530	4008202	4096833	4179344	4380999
			3904671	4015532	4107580	4185410	4388127
			3904672	4018506	4110437	4196262	4389878
			3920942	4026690	4128016	4213411	4395762
			3930012	4035709	4138999	4279324	4399141
995102	67PFP40	TUBE, TRACH PEDIATRIC 4.0 TTS FLEXTEND PLUS V FLANGE	3868327	4035694	4159948	4240126	4348414
			3930013	4096834	4185407	4334895	4388111
			3952350	4134018			
995104	67PFP45	TUBE, TRACH PEDIATRIC 4.5 TTS FLEXTEND PLUS V	3880709	3939673	4035696	4086000	4348416
			3920941	3959299	4063166	4334896	4357247
995105	67PFP50	TUBE, TRACH PEDIATRIC 5.0 TTS FLEXTEND PLUS V FLANGE	3853394	3930055	4005587	4105261	4176226
			3877669	3936567	4026685	4119098	4328213
			3897878	3936568	4043939	4138983	4334900
			3914570	3981982	4066291	4156623	4400630
			3923744				
995106	67PFP55	TUBE, TRACH PEDIATRIC 5.5 TTS FLEXTEND PLUS V FLANGE	3897866	4083921	4171576	4352769	4383601
			3923732	4145687	4237354	4374408	4395748
			4035697	4159967	4331568		
1008893	67PFSS45	TUBE, TRACH BOVINA FLEXTEND STRT NECK PED 4.5	3853425	3965915	4086020	4204808	4334954
			3868277	3982051	4091398	4212768	4334955
			3868279	3982052	4092644	4216318	4334956
			3868280	3987967	4096843	4217438	4334957
			3868281	3988069	4097817	4231489	4334972
			3877663	3991136	4107605	4233955	4344989
			3880682	4005616	4110441	4237372	4344990
			3880683	4005617	4116098	4237373	4344991
			3887714	4011371	4122432	4237374	4355425
			3894879	4014485	4128040	4240137	4355427
			3901283	4014486	4130983	4247287	4355428
			3904662	4029501	4134033	4254228	4362860
			3907980	4033715	4138981	4267847	4362861
			3930018	4035720	4145684	4273423	4374418
			3936580	4040574	4147991	4279329	4374419
			3939682	4043941	4151039	4279330	4380077
3939683	4048034	4156622	4279331	4380078			



MMS #	MFG Catalog #	Description	Affected Lot(s)				
1008893	67PFSS45	TUBE, TRACH BOVINA FLEXTEND STRT NECK PED 4.5	3939684	4053700	4159966	4283231	4383615
			3942525	4056248	4163830	4283232	4383616
			3942526	4063176	4168136	4283233	4388139
			3942527	4066290	4176231	4292162	4388140
			3955763	4070849	4179350	4322666	4388141
			3965912	4077076	4196268	4322667	4389887
			3965913	4080797	4197610	4327920	4393402
			3965914	4083919	4201367	4327921	4393403
1012571	67PFPS60	TUBE, TRACH PEDIATRIC 6.0 TTS FLEXTEND PLUS STRT FLANGE	3802149	3914572	4021419	4095926	4254220
			3802150	3917992	4023782	4100901	4334907
			3832051	3917993	4029495	4110434	4352771
			3853402	3942540	4033707	4119104	4374409
			3871040	3942541	4035705	4142440	4380996
			3874313	3959322	4038944	4163846	4380997
			3880685	3981987	4053728	4176249	4380998
			3887730	3981989	4071977	4185409	4383605
			3894912	3987944	4077106	4197605	4400634
			3907974	4008200	4083927	4237358	4319265-ENG
3907975	4018502	4091407	4240128				
1018037	67NFPS35	TUBE, TRACH NEONATAL FLEXTEND TTS W/CUFF STRT FLNG 3.5"	3853384	3965911	4077075	4179338	4334221
			3853385	3981974	4086019	4216300	4334225
			3868267	3981975	4092642	4218693	4334226
			3871038	3997793	4097824	4237349	4344970
			3880695	3997794	4107604	4237350	4348410
			3884238	4011357	4110431	4260048	4348411
			3891516	4018496	4116106	4260049	4357245
			3894911	4023777	4125811	4273412	4358489
			3904649	4035689	4128038	4276444	4358490
			3911417	4035690	4134032	4286788	4389868
			3926972	4051622	4145682	4322654	4389869
			3939651	4053705	4147988	4327908	4395741
			3942536	4063162	4159958	4329829	4399127
			3952411	4066292	4168141	4331558	4400625
			3959324				
1031596	67PFP60	TUBE, TRACH FLEXTEN PED 6.0	3802151	3917991	4001127	4056250	4151057
			3828304	3930054	4023778	4060222	4161985
			3853395	3939650	4029494	4071968	4176242
			3877668	3946263	4035699	4083920	4328214
			3887728	3955813	4038943	4086014	4331569
			3901296	3955814	4043940	4095924	4334902
			3917990	3962593	4051663	4128029	4388112
1037928	60PFPS45	TUBE, TRACH BIVONA FLEXTEND PLUS STRT NECK FLANGE PED 4.5MM	3868257	3949033	4077109	4171547	4335000
			3868258	3955791	4086027	4179356	4348467
			3877672	3962587	4089291	4180469	4348470
			3880693	3982665	4093735	4196277	4358484

MMS #	MFG Catalog #	Description	Affected Lot(s)				
1037928	60PFPS45	TUBE, TRACH BIVONA FLEXTEND PLUS STRT NECK FLANGE PED 4.5MM	3891520	3982666	4110451	4212778	4383625
			3904652	4008217	4125815	4223728	4389898
			3914574	4015541	4134023	4231497	4393407
			3926970	4035737	4151043	4237383	4395784
			3931142	4049432	4159947	4292165	4399176
			3942520	4063184	4161983	4331608	4400666
1052462	67PFSS30	TRACH, BIVONA FLEXTEND STRT NECK 3.0 PED	3853409	3961758	4089295	4212764	4357250
			3853410	3981997	4095916	4217436	4358491
			3868326	3981998	4096830	4254222	4358492
			3871053	3987959	4110438	4273418	4374413
			3877650	3991133	4116085	4276454	4380076
			3887740	4005597	4136131	4279325	4381001
			3897845	4011365	4138990	4322661	4383608
			3923723	4035710	4156656	4329839	4388129
			3931154	4051637	4159994	4334936	4388130
			3939667	4051638	4171580	4344353	4389879
			3939668	4063173	4171581	4344981	4393395
			3946281	4071984	4185411	4348422	4395763
			3959294	4075246	4195802	4357249	4399143
			3961757				
1052463	67PFPS45	TRACH, BIVONA FLEXTEND + STRT FLANGE 4.5 PED	3853399	3952415	4041959	4153608	4333981
			3864259	3952416	4048016	4161964	4334904
			3871049	3965904	4053711	4173724	4348418
			3880700	3981981	4060204	4176222	4358480
			3887735	3997802	4077079	4218697	4358481
			3894893	3997803	4089300	4237357	4383604
			3904657	4011362	4096828	4240127	4388115
			3917998	4018501	4107614	4276449	4388116
			3920966	4026672	4116110	4286794	4395751
			3931144	4033705	4136124	4289467	4399134
			3936564	4035703	4145679	4331571	4400632
3942550							
1057201	67PFPS50	TUBE, TRACH FLEXTEND PLUS STRAIGHT FLANGE 5.0 TTS	3853400	3920958	4023780	4128041	4260056
			3868255	3920959	4033706	4138975	4292158
			3868256	3930023	4035704	4145689	4322658
			3871037	3930025	4048031	4151042	4329834
			3877662	3946300	4051664	4156625	4334223
			3887725	3955761	4063168	4161977	4358477
			3891536	3965917	4083922	4173725	4358478
			3894881	3981984	4086013	4213404	4393392
			3907982	3981985	4092643	4216310	4395752
			3918012	4015529	4097826	4254218	4399135
			3920957				



MMS #	MFG Catalog #	Description	Affected Lot(s)				
1061822	67PFSS50	TUBE, TRACH PEDIATRIC 5.0 FLEXTTS STRAIGHT NECK	3840077	3946256	4063177	4196269	4329828
			3868270	3959320	4070850	4197611	4331593
			3868271	3959321	4077107	4201368	4334219
			3874322	3965926	4083933	4204809	4334958
			3880686	3982053	4095913	4213414	4344343
			3891521	3982055	4100898	4233956	4344344
			3894913	3997807	4116099	4247288	4348423
			3894914	4005627	4125805	4254229	4348424
			3897875	4011372	4130999	4260064	4353079
			3914573	4023785	4138977	4267848	4353080
			3917988	4029502	4142439	4279332	4369579
			3926973	4033716	4151056	4283234	4369580
			3930051	4035724	4156645	4289474	4369581
			3939654	4038945	4159982	4289475	4369582
			3939655	4043942	4163847	4292163	4383617
			3939656	4051668	4176241	4322668	4383618
			3942535	4056244	4180480	4328220	4388142
			3946255				
1102394	67PFPS40	TUBE, TRACH PORTEX BIVONA FLEXTEND STRT NECK FLANGE 4MM PED	3853396	3955815	4066299	4171577	4344976
			3853397	3959315	4092625	4180482	4348417
			3853398	3959316	4100899	4196258	4358474
			3868287	3959317	4107607	4216309	4358475
			3877646	3988071	4113098	4218696	4362844
			3887734	4011361	4119102	4237356	4380995
			3894892	4023779	4125822	4260055	4383602
			3901306	4033704	4130993	4276448	4388113
			3917987	4035702	4136123	4286793	4388114
			3920965	4041960	4145709	4292157	4389872
			3926974	4051672	4156646	4331570	4395749
			3939653	4053712	4159981	4334903	4399133
			3942530				
1124992	60PFPS55	TUBE, TRACH CUFFLESS PED 5.5MM	3955798	4035739	4110452	4223729	4347206
			3991156	4053730	4128034	4237384	4358487
			4015543	4080794	4139022	4331612	4388166
			4026692	4097835	4151025	4335002	4399178
1127829	67PFPS55	TUBE, TRACH BIVONA FLEXTEND TTS PLUS STRT NECK PED 5.5	3853401	4086012	4142445	4185408	4329835
			4005589	4092645	4145683	4196259	4334224
			4011363	4097827	4153625	4213405	4344977
			4021414	4113102	4156624	4254219	4369560
			4023781	4119092	4159961	4276450	4388117
			4043936	4130982	4173726	4279322	4399136
1127979	67NFPS40	TUBE, TRACH BIVONA FLEXTEND TTS STRT NECK FLANGE NEO 4.0	4063169	4138982	4179341	4327892	
			3887729	3962592	4035691	4148020	4334227
			3936565	3997795	4051669	4163840	4352760
3939648	4001125	4060199	4217431	4358476			

MMS #	MFG Catalog #	Description	Affected Lot(s)				
1127979	67NFPS40	TUBE, TRACH BIVONA FLEXTEND TTS STRT NECK FLANGE NEO 4.0	3939649	4011358	4089292	4237351	4362841
			3942543	4016058	4119106	4240123	4395743
			3946254	4026675	4130998	4276445	4399128
			3952409	4029493	4145708		
1128658	67NFPS30	TUBE, TRACH BIVONA FLEXTEND TTS STRT NECK FLANGE NEO 3.0	3853383	3981972	4051670	4142441	4329830
			3877674	3981973	4060197	4148024	4334222
			3884243	3997792	4080786	4185404	4344969
			3891517	4001124	4089289	4213399	4352759
			3901295	4008198	4095914	4217430	4369536
			3917994	4018495	4105262	4254214	4369537
			3930044	4023776	4107608	4276443	4369538
			3939657	4029492	4119105	4292152	4388102
			3942542	4035686	4125806	4322653	4395740
			3952413	4035688	4134038	4327895	4400623
			3952414				
1140683	67NFPS25	TUBE, TRACH BIVONA SIL STRT NEO 2.5MMX30MM	3880680	4038941	4372091	4372093	4395738
			4038940	4327879	4372092	4388100	
1170702	67PFSS25	TRACH, TUBE BIVONA PED STRT FLEXTEND 2.5	3923743	4016053	4080314	4217435	4374412
			4005596	4016057	4087038	4334932	
446568 450021	670170	TUBE, TRACH TTS CUFF 7.0MM (6/BX)	3782491	3904468	4039104	4156741	4267576
			3782492	3907878	4042006	4160050	4267577
			3790088	3912930	4046818	4160052	4270314
			3790091	3914526	4049983	4162043	4270316
			3790097	3917902	4049984	4162044	4270317
			3797103	3920858	4056268	4163859	4270318
			3797105	3929863	4067201	4171673	4270319
			3797109	3935867	4067202	4173689	4270320
			3797113	3939399	4067204	4178826	4273058
			3797116	3939406	4067548	4180535	4279290
			3800543	3939407	4070873	4180536	4279291
			3800545	3939411	4070875	4185491	4283177
			3800550	3939414	4071068	4187479	4283178
			3800553	3952178	4071076	4196306	4285196
			3801604	3952186	4083954	4196307	4285197
			3801607	3952190	4086069	4201728	4287988
			3801609	3965935	4086070	4201732	4290373
			3801611	3965938	4089223	4205246	4291369
			3801613	3984875	4092682	4205247	4293836
			3801615	3984881	4092683	4212852	4293838
			3801617	3984885	4095936	4216353	4293839
			3801618	3984888	4095937	4216354	4293840
			3801622	3984891	4095938	4218784	4293841
			3801623	3984909	4096878	4221380	4299846
			3801633	3984915	4101020	4226280	4331664
			3801634	3984916	4105308	4229359	4331665



MMS #	MFG Catalog #	Description	Affected Lot(s)				
446568 450021	670170	TUBE, TRACH TTS CUFF 7.0MM (6/BX)	3801635	3984919	4105310	4231601	4331666
			3828106	3984921	4105311	4231602	4331667
			3828116	3988229	4105312	4231603	4335524
			3831839	3988232	4105313	4233992	4335527
			3831840	3988233	4107648	4233993	4335528
			3831847	3991241	4111659	4240186	4345527
			3831853	3991247	4111660	4240187	4346815
			3839640	3991250	4111662	4242050	4346817
			3845084	3997995	4111664	4242052	4346819
			3870000	3997996	4111665	4244548	4346821
			3870005	3997999	4111666	4244549	4362631
			3870011	4002330	4113158	4244550	4362632
			3870016	4002332	4116179	4248368	4362635
			3870019	4002335	4116180	4248369	4367632
			3870026	4002336	4119138	4254426	4367633
			3870028	4002337	4119140	4254427	4371685
			3870032	4002340	4119141	4255457	4371686
			3870033	4002342	4122545	4255458	4371687
			3870036	4002347	4128102	4257846	4372363
			3870038	4002349	4131091	4257847	4372364
			3874192	4002351	4131092	4257848	4372365
			3874202	4005733	4134129	4257849	4376158
			3889882	4005734	4136193	4257850	4376159
			3890403	4005735	4136194	4257851	4376160
			3890404	4005736	4139037	4257852	4382326
			3890407	4005744	4139039	4263219	4382330
			3890409	4005745	4139040	4263220	4382331
			3891452	4005746	4142478	4263221	4384899
			3894687	4005748	4142479	4263222	4384900
			3894691	4011404	4145804	4265144	4384901
			3897734	4011405	4145805	4267569	4384902
			3897738	4011406	4148058	4267570	4384903
			3901125	4011407	4148060	4267571	4384904
3901128	4011408	4151117	4267572	4384905			
3901145	4015635	4151118	4267573	4384906			
3904465	4039103	4153689	4267575				
446586 446587	60P050	TUBE, TRACH PED SZ5	3858169	3918021	4015587	4179370	4327947
			3861127	3918022	4027994	4196296	4331637
			3868289	3926969	4027995	4204825	4335070
			3868290	3942507	4040758	4206843	4335071
			3868291	3946271	4040759	4209585	4335072
			3894909	3952401	4077068	4209586	4335073
			3897860	3952402	4085997	4216335	4345042
			3904658	3952403	4085998	4218720	4351251
			3911428	3955781	4092634	4218721	4352804

MMS #	MFG Catalog #	Description	Affected Lot(s)				
446586 446587	60P050	TUBE, TRACH PED SZ5	3911429	3982706	4097839	4221359	4369620
			3930056	3982707	4107583	4226271	4374479
			3942490	3982708	4107584	4254279	4374480
			3946246	3988158	4113118	4254280	4380057
			3949024	3988159	4122446	4273442	4382709
			3853484	3988160	4125824	4276482	4383657
			3868201	3988161	4136147	4279348	4388210
			3868202	3991205	4139000	4283257	4388211
			3871066	3997823	4147981	4283258	4389928
			3884260	4005680	4151023	4286819	4393426
			3891527	4005681	4159937	4289496	4395804
			3894890	4005682	4168184	4292182	4399218
			3904663	4015583	4173735	4322689	4400699
			3904664	4015586			
			942295 816531	67SP035	TUBE, TRACH TTS CUFF PED 3.5MM	3894891	4051662
3901311	4066294	4153606				4289477	4362880
3926976	4077067	4163818				4322669	4369585
3942450	4086030	4180462				4331584	4369586
3942451	4119122	4204811				4334963	4369587
3997809	4125830	4213415				4348433	4400655
4012664							



McKesson Medical-Surgical Inc.
 Field Safety Reply Form: RC-2024-141
 Smiths Medical Various Tracheostomy Tubes

June 14, 2024

Complete this reply form and return all pages immediately via email to MMSRecalls@McKesson.com or fax at **(866) 871-0270** should you have affected product.

To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.

Date: _____

Your Name: _____ Email Address: _____

Phone Number: _____ Fax Number: _____

Account: 58195501 District: 20040000
 LIFE LINE HC TIFTON
 ATTN: RISK MANAGEMENT
 1804 TIFT AVE N
 TIFTON, GA 31794-3542

I acknowledge that I DO HAVE product affected by this notification and have followed the instructions for disposal from Sedgwick. I have not requested replacement product from Sedgwick.

Qty	Unit of Measure	Affected Lot #(s)	MMS #	MFG Catalog #	Description
			368143	60PFS40	TUBE, FLEXTEND TRACH PED 4.0MM60PF40
			368144	60PFS45	TUBE, FLEXTEND TRACH PED 4.5MM60PF45
			368146	67P035	TUBE, TRACH TTS PED 3.5MM
			493829	60P025	TUBE, TRACH UNCUFF PED SZ2.5 (1/BX)
			493830	60P030	TUBE, TRACH UNCUFF PED 3.0MM (1/BX)
			368147	67P040	TUBE, TRACH TTS PED 4.0MM
			368148	67P045	TUBE, TRACH TTS PED 4.5MM
			368149	67P050	TUBE, TRACH TTS PED 5.0MM
			368150	67P055	TUBE, TRACH TTS PED 5.5MM
			950547	67PFSS55	TUBE, TRACH PEDIATRIC 5.5ML TTS
			1061822	67PFSS50	TUBE, TRACH PEDIATRIC 5.0 FLEXTTS STRAIGHT NECK
			1012571	67PFPS60	TUBE, TRACH PEDIATRIC 6.0 TTS FLEXTEND PLUS
			468383	670180	TUBE, TRACH TTS CUFFED ADLT 8.0MM
			468385	750160	TUBE, TRACH MID-RANGE AIRE-CUFF 6.0MM
			468386	750170	TUBE, TRACH MID-RANGE AIRE-CUFF 7.0MM
			468387	750180	TUBE, TRACH MID-RANGE AIRE-CUFF 8.0MM
			511325	67N025	TUBE, TRACH NEONATAL 2.5
			513858	65N030	TUBE, TRACH CUFFED NEONATAL SZ3
			816485	60NFP25	TUBE, TRACH FLEXTEND+ UNCUFF NEONATE 2.5MM
			816486	60PFP40	TUBE, TRACH FLEXTEND+ UNCUFF LNG PED 4.0MM
			816487	60PFP50	TUBE, TRACH FLEXTEND+ UNCUFF LNG PED 5.0MM
			842572	60PFSS35	TUBE, TRACH BIVONA FLEXTEND+ UNCUFF STRT PED
			844008	60NFPS30	TUBE, TRACH NEONATAL/PED FLEXTEND+ SIL 3.0MM
			854107	60NFPS40	TUBE, TRACH NEONATAL 4.0MM



Qty	Unit of Measure	Affected Lot #(s)	MMS #	MFG Catalog #	Description
			995083	67NFP25	TUBE, TRACH NEONATAL 2.5 TTS FLEXTEND V FLANGE
			995104	67PFP45	TUBE, TRACH PEDIATRIC 4.5 TTS FLEXTEND PLUS V
			1018037	67NFPS35	TUBE, TRACH NEONATAL FLEXTEND TTS W/CUFF STRT
			995067	60PFSS50	TUBE, TRACH PEDIATRIC FLEXTENDSTANDARD
			995105	67PFP50	TUBE, TRACH PEDIATRIC 5.0 TTS FLEXTEND PLUS V
			368142	60PFS35	TUBE, FLEXTEND TRACH PED 3.5MM60PF35
			651877	60NFP30	TUBE, TRACH FLEXTEND+ NEO 3.0MM
			368145	67N035	TUBE, TRACH TTS NEO 3.5MM
			446581	60N035	TUBE, TRACH NEO SZ3.5
			995087	67NFP35	TUBE, TRACH NEONATAL 3.5 TTS FLEXTEND VS FLANGE
			995080	60PFSS55	TUBE, TRACH PEDIATRIC FLEXTENDSTD STRT 5.5MM
			995097	67PFS40	TUBE, TRACH PEDIATRIC 4.0 TTS FLEXTEND V NECK
			995090	67NFP40	TUBE, TRACH NEONATAL 4.0 TTS FLEXTEND V FLANGE
			1008893	67PFSS45	TUBE, TRACH BOVINA FLEXTEND STRT NECK PED 4.5
			867114	60PFSS30	TUBE, TRACH BIONA FLEXTEND + UNCUFFED STD STRT
			921906	67PFSS35	TUBE, TRACH PED W/FLEX TEND 3.5
			446568	670170	TUBE, TRACH TTS CUFF 7.0MM (6/BX)
			446579	60N030	TUBE, TRACH NEO SZ3.0
			446580	60N025	TUBE, TRACH NEO SZ2.5
			446582	60N040	TUBE, TRACH NEO SZ4
			446583	60P035	TUBE, TRACH PED SZ3.5
			446584	60P040	TUBE, TRACH PED SZ4
			446585	60P045	TUBE, TRACH PED SZ 4.5
			446588	60P055	TUBE, TRACH PED SZ5.5
			816517	65SN040	TUBE, TRACH AIRE-CUFF STRT FLANGE NEO 4.0MM
			816518	65SP025	TUBE, TRACH AIRE-CUFF STRT FLANGE NEO 2.5MM
			1057201	67PFPS50	TUBE, TRACH FLEXTEND PLUS STRAIGHT FLANGE 5.0
			1052462	67PFSS30	TRACH, BIVONA FLEXTEND STRT NECK 3.0 PED
			1052463	67PFPS45	TRACH, BIVONA FLEXTEND + STRT FLANGE 4.5 PED
			691131	60PFP55	TUBE, FLEXTEND TRACH PED 5.5MM
			543687	65P030	TUBE, TRACH BIVONA CUFFED PED 3.0
			543688	65P035	TUBE, TRACH BIVONA CUFFED PED 3.5
			543689	65N025	TUBE, TRACH BIVONA CUFFED NEONATAL 2.5
			543690	65N035	TUBE, TRACH BIVONA CUFFED NEONATAL 3.5
			543691	65N040	TUBE, TRACH BIVONA CUFFED NEONATAL 4.0
			543692	67P025	TUBE, TRACH BIVONA CUFFED TTS PED 2.5
			543693	67P030	TUBE, TRACH BIVONA CUFFED TTS PED 3.0
			484460	67N040	TUBE, TRACH NEO 4.0
			942295	67SP035	TUBE, TRACH TTS CUFF PED 3.5MM
			943871	67PFSS40	TRACHEOSTOMY, PEDIATRIC TTS F LEXTEND STRAIGHT
			580731	60NFP40	TUBE, TRACH SIL 4.0MM+
			583096	60NFP35	TUBE, TRACH SIL 3.5 PED
			847284	60NFPS35	TUBE, TRACH NEO 3.5MM STRT FLEXTEND BIVONA
			843298	60PFPS40	TUBE, TRACH FLEXTEND+ PED 4.0MM
			1127829	67PFPS55	TUBE, TRACH BIVONA FLEXTEND TTS PLUS STRT NECK



Qty	Unit of Measure	Affected Lot #(s)	MMS #	MFG Catalog #	Description
			1124992	60PFPS55	TUBE, TRACH CUFFLESS PED 5.5MM
			1140683	67NFPS25	TUBE, TRACH BIVONA SIL STRT NEO 2.5MMX30MM
			683057	60PFP45	TUBE, TRACH FLEX PLUS 4.5MM
			714195	60SN035	TUBE, TRACH UNCUFFED 3.5MM
			714196	60SN040	TUBE, TRACH UNCUFFED 4.0MM
			796549	60PFPS60	TUBE, TRACH BIVONA NEO SIL 6.0AMESMI
			796353	60PFPS50	TUBE, TRACH BIVONA N/CUFF PED SZ5
			1031596	67PFP60	TUBE, TRACH FLEXTEN PED 6.0
			995047	60NFPS25	TUBE, TRACH UNCUFFED NEONATAL FLEXTEND
			535918	65P040	TUBE, TRACH CUFF PED 4.0MM
			535919	65P045	TUBE, TRACH CUFF PED 4.5MM
			535920	65P050	TUBE, TRACH CUFF PED 5.0MM
			535921	65P055	TUBE, TRACH CUFF PED 5.5MM
			815763	67SP055	TUBE, TRACH W/CUFF PED 5.5MM W/STRT NECK
			816519	65SP030	TUBE, TRACH AIRE-CUFF STRT FLANGE NEO 3.0MM
			816520	65SP035	TUBE, TRACH AIRE-CUFF STRT FLANGE NEO 3.5MM
			816521	65SP040	TUBE, TRACH AIRE-CUFF STRT FLANGE NEO 4.0MM
			816522	65SP045	TUBE, TRACH AIRE-CUFF STRT FLANGE PED 4.5MM
			816523	65SP050	TUBE, TRACH AIRE-CUFF STRT FLANGE PED 5.0MM
			816524	65SP055	TUBE, TRACH AIRE-CUFF STRT FLANGE PED 5.5MM
			816525	67SN025	TUBE, TRACH TTS CUFF STRT FLANGE NEO 2.5MM
			816526	67SN030	TUBE, TRACH TTS CUFF STRT FLANGE NEO 3.0MM
			816527	67SN035	TUBE, TRACH TTS CUFF STRT FLANGE NEO 3.5MM
			816528	67SN040	TUBE, TRACH TTS CUFF STRT FLANGE NEO 4.0MM
			816529	67SP025	TUBE, TRACH TTS CUFF STRT FLANGE PED 2.5MM
			816530	67SP030	TUBE, TRACH TTS CUFF STRT FLANGE PED 3.0MM
			816531	67SP035	TUBE, TRACH TTS CUFF STRT FLANGE PED 3.5MM
			816532	67SP040	TUBE, TRACH TTS CUFF STRT FLANGE PED 4.0MM
			816533	67SP045	TUBE, TRACH TTS CUFF STRT FLANGE PED 4.5MM
			816617	60SN025	TUBE, TRACH UNCUFF STRT FLANGENE0 2.5MM
			816618	60SN030	TUBE, TRACH UNCUFF STRT FLANGENE0 3.0MM
			816619	60SP025	TUBE, TRACH UNCUFF STRT FLANGEPED 2.5MM
			816620	60SP030	TUBE, TRACH UNCUFF STRT FLANGEPED 3.0MM
			816621	60SP035	TUBE, TRACH UNCUFF STRT FLANGEPED 3.5MM
			816622	60SP040	TUBE, TRACH UNCUFF STRT FLANGEPED 4.0MM
			816623	60SP055	TUBE, TRACH UNCUFF STRT FLANGEPED 5.5MM
			816624	65P025	TUBE, TRACH AIRE-CUF 4MM OD 38MM LNG PED
			816625	65SN025	TUBE, TRACH AIRE-CUF STRT FLANGE NEO SZ2.5
			816626	65SN030	TUBE, TRACH AIRE-CUF STRT FLANGE NEO SZ3
			816627	65SN035	TUBE, TRACH AIRE-CUF STRT FLANGE NEO SZ3.5
			817490	60PFP60	TUBE, TRACH VEE FLEXTEND PED PLUS 6.0MM
			650073	60SP050	TUBE, TRACH BIVONA W/STR FLNG UNCUFF PED
			511326	67N030	TUBE, TRACH NEONATAL 3.0
			446586	60P050	TUBE, TRACH PED SZ5



Qty	Unit of Measure	Affected Lot #(s)	MMS #	MFG Catalog #	Description
			1102394	67PFPS40	TUBE, TRACH PORTEX BIVONA FLEXTEND STRT NECK
			995065	60PFSS40	TUBE, TRACH UNCUFFED PEDIATRICSTD STRT 4.0MM
			995084	67NFP30	TUBE, TRACH NEONATAL 3.0 TTS FLEXTEND V
			995098	67PFS45	TUBE, TRACH PEDIATRIC 4.5 TTS FLEXTEND V NECK
			995094	67PFS30	TUBE, TRACH PEDIATRIC 3.0 TTS FLEXTEND V NECK
			995100	67PFS55	TUBE, TRACH PEDIATRIC 5.5 TTS FLEXTEND V NECK
			995106	67PFP55	TUBE, TRACH PEDIATRIC 5.5 TTS FLEXTEND PLUS V
			995095	67PFS35	TUBE, TRACH PEDIATRIC 3.5 TTS FLEXTEND V NECK
			726792	60SP045	TUBE, TRACH N/CUFF PED SZ4.5
			408489	60PFS25	TUBE, FLEXTEND TRACH PED 2.5MM60PF25
			408490	60PFS30	TUBE, FLEXTEND TRACH PED 3.0MM60PF30
			408491	60PFS50	TUBE, FLEXTEND TRACH PED 5.0MM60PF50
			408492	60PFS55	TUBE, FLEXTEND TRACH PED 5.5MM60PF55
			1128658	67NFPS30	TUBE, TRACH BIVONA FLEXTEND TTS STRT NECK
			1127979	67NFPS40	TUBE, TRACH BIVONA FLEXTEND TTS STRT NECK
			663123	67SP050	TUBE, TRACH CUFFED STRT FLANGEPED SZ5
			726160	60PFSS45	TUBE, FLEXTEND TRACH PED 4.5MM
			446587	60P050	TUBE, TRACH PED SZ5.0
			1037928	60PFPS45	TUBE, TRACH BIVONA FLEXTEND PLUS STRT NECK
			995099	67PFS50	TUBE, TRACH PEDIATRIC 5.0 TTS FLEXTEND V NECK
			995102	67PFP40	TUBE, TRACH PEDIATRIC 4.0 TTS FLEXTEND PLUS V
			995062	60PFSS25	TUBE, TRACH UNCUFFED PEDIATRICFLEXTEND 2.5MM
			450021	670170	TUBE, TRACH TTS CUFF 7.0MM
			1170702	67PFSS25	TRACH, TUBE BIVONA PED STRT FLEXTEND 2.5

*Discard affected lot numbers only

* The affected lot numbers are listed on Attachment 1.

- **Please note:** Prior to submission of this Reply Form to the McKesson Corporate Customer Service Center, contact Sedgwick at **1-888-628-0731** or via email via email at smithsmedical3513@sedgwick.com to obtain a Response Form. Please indicate you are a McKesson Medical Surgical Customer when requesting the form.
- **Please enter** the Reference ID # provided by Sedgwick: _____

Your submitted McKesson Reply Form must include the Reference ID # provided by Sedgwick to receive credit.

If you have any questions about information provided in this communication, please contact the McKesson Recall Message Center at MMSRecalls@McKesson.com or call (800) 688-8840.

See instructions on the reverse side of this form to access McKesson Medical-Surgical's online product ordering system, "SupplyManager", for a fillable form.

Instructions for the McKesson Medical-Surgical online product ordering system – “SupplyManager”, to access and download a “fillable” PDF reply form.

- 1) It is important to download the correct reply form for the specific recall you are responding to.
 - a. Reply forms have a specific designation, example: RC-202X-XXX.
 - “202X” is the recall year, and “XXX” is the 3-digit unique numeric identifier for the recall.
- 2) Go to <https://mms.mckesson.com/> and log in to “SupplyManager”, with your username and password.
- 3) On the home page, under ‘Essential Tasks’ click ‘Your Account.’ Under ‘Resources’ a support link titled “Product Recalls” can be found on the right side.
- 4) Click on the hyperlink “Product Recalls” (this will open a listing of recalls for the last 3 months).



- 5) On the recalls list page, locate the “Find” box.
 - a. From the drop-down options, select one of the following: “Keyword”, “McKesson Item #” or “Manufacturer”.
 - b. Enter a Keyword, McKesson Item #, or Manufacturer name in the Find box and click “Find”.

Find Manufacturer ▼ Find Clear

- c. A list of issued recalls will be made visible for you to select from.
- 6) Click on the blue hyperlink, found under the heading “Recall Notice,” for the notice details you want to access.

Manufacturer	Recall Notice	Issued ▼
--------------	---------------	----------

- 7) The PDF customer documents associated with the notice will be displayed, *this includes the reply form to download and complete for your response.*
- 8) Click on the hyperlink(s) to open the Customer Document(s). Save/Download this document to your computer. Once the documents are saved, close out the document window.
- 9) Submit completed reply form to MMSRecalls@McKesson.com.
- 10) If you wish to view additional recalls, return to the home recall page by clicking the blue “View All Recalls” button at the upper right corner of the page above the blue alert banner.

URGENT MEDICAL DEVICE NOTIFICATION

Bivona® Aire-Cuf®, TTS™, Uncuffed, Mid-Range Neonatal/Pediatric Tracheostomy Tube(s) and Bivona Aire-Cuf®, TTS™, Cuffless FlexTend™, TTS™ FlexTend™ Adult Tracheostomy Tube(s)

29 May 2024:

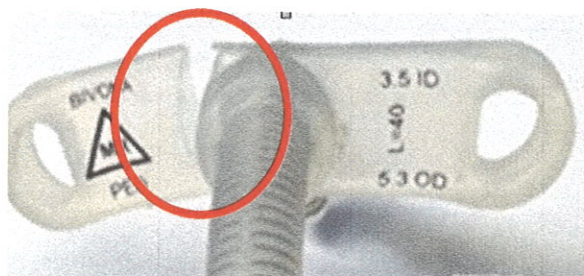
Dear Valued Bivona® Customers:

- Director of Biomedical Engineering
- Director of Nursing
- Director of Risk Management

Smiths Medical issuing this Urgent Field Safety Notice to notify you of a potential defect with the following Bivona® Neonatal/Pediatric and Adult Tracheostomy products listed in Attachment 1_Affected Product. This letter details the issue and the required steps for you to complete.

Issue:

Smiths Medical has identified that the securement flange of specific lots of the Bivona® Neonatal/Pediatric and Adult Tracheostomy products may tear because of a manufacturing defect. See picture below for an example of a torn flange.



Potential Risk:

If the flange on the item is torn or broken, the tracheostomy tube may not stay in position in the trachea. This can lead to tracheostomy displacement or decannulation. Either event may result in an inability to properly ventilate or protect the airway. Either can contribute to a catastrophic adverse event. To date, Smiths Medical has received thirty-five (35) reports of serious injury and one (1) death associated with this issue.

Affected Product:

Please see the affected item and lot numbers in Attachment 1_Affected Product List.

Smiths Medical Action:

Smiths Medical is sending this notification to all Bivona® customers who received products from Smiths Medical listed in Attachment 1_Affected Product. Smiths Medical will provide replacement product(s) and/or credit affected customers. Please contact your local representative with your certificate of destruction to coordinate the replacement/credit.

Customer Required Actions:

When using the device, all instructions, including warning and cautions contained in the Instructions for Use Documentation must be followed with heightened awareness. Please complete the following actions listed below:

1. Check all inventory locations within your institution for the affected catalog numbers listed in the notification and discontinue use. Discard all affected products following your institution's process for discarding. If discarding is not immediately possible at your facility, then the product should be quarantined until disposal.
2. Share this notification with all potential users of the devices to ensure they are aware of this notification and proposed mitigations. If the devices are used at another location, please ensure this communication is delivered there.
3. Complete and return the attached Customer Response Form to smithsmedical3513@sedgwick.com **within 10 days of receipt** to acknowledge your understanding of this notification. Please contact your local representative for assistance with replacement product and/or credit.
3. DISTRIBUTORS: If you have distributed potentially affected products to your customers, please immediately forward this notice to them. Request that they complete the response form and return it to smithsmedical3513@sedgwick.com

If you have any questions regarding product replacement and/or credit, please contact Smiths Customer Service below.

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	1-(866)-216-8806 or US: globalcomplaints@icumed.com	To report adverse events or product complaints
Customer Service	Customerservice@icumed.com 1-(800)-258-5361	Questions about your product replacement and/or credit

This notification is being performed with the knowledge of regulatory authorities, including the US Food and Drug Administration (FDA).

If you wish to contact the FDA regarding any adverse events or quality problems associated with this notice, use the following contact information.

- www.fda.gov/medwatch
- 1-(888)-INFO-FDA

Smiths Medical is committed to patient safety and is focused on providing exceptional product reliability and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,



Andy Mathein
Vice President of Quality

Enclosures:

- Customer Response Form
- ~~Attachment 1_Affected Product~~