

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)**

24 MAY 2024:

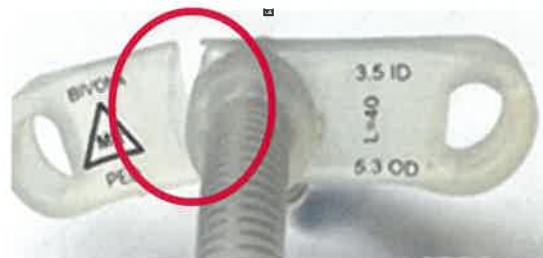
Dear Valued Bivona® Customers:

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

Smiths Medical is 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 or the distributor where the product was purchased 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 or the distributor where the product was purchased for assistance with replacement product and/or credit.
4. 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 Smith's Customer Service below:

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	canadacomplaints@icumed.com 1-(866)-216-8806	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 Health Canada.

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,



Sebastien Geoffroy
Quality Manager, Canada

Enclosures:

- Customer Response Form

Attachment 1_Affected Product List

Part number	Description	Lot
670170	TTS TRACHEOSTOMY TUBE 7.0MM TIGHT TO SHAFT CUFF	3782489, 3790082, 3797112, 3797114, 3800540, 3800542, 3870036, 3870979, 3874196, 3874198, 3889864, 3889868, 3889869, 3889877, 3890392, 3890393, 3890407, 3890409, 3894681, 3894684, 3894691, 3901138, 3904461, 3914525, 3914526, 3914528, 3939399, 3939402, 3939411, 3952159, 3952178, 3952186, 3965935, 3984881, 3984885, 3984902, 3984905, 3984909, 3984912, 3984919, 3984920, 3988229, 3988233, 3991247, 4002331, 4002332, 4002335, 4002345, 4002350, 4005735, 4005736, 4011407, 4042003, 4042006, 4056268, 4067202, 4067216, 4070875, 4071068, 4071076, 4086069, 4092682, 4105310, 4105311, 4107648, 4111659, 4111661, 4111666, 4116180, 4119141, 4122544, 4134127, 4134130, 4136193, 4139037, 4145804, 4148057, 4148058, 4148061, 4151118, 4151119, 4151120, 4153687, 4156740, 4162043, 4168076, 4168132, 4171671, 4187479, 4242050, 4244548, 4244549, 4254427, 4255457, 4257847, 4263220, 4267571, 4267574, 4267575, 4267576, 4267577, 4270314, 4270316, 4270320, 4270321, 4273057, 4273058, 4279290, 4279291, 4283177, 4285196, 4287988, 4291370, 4293836, 4293838, 4299057, 4331666, 4335526, 4345527, 4346815, 4346819, 4376158, 4382326
670180	TTS TRACHEOSTOMY TUBE 8.0MM TIGHT TO SHAFT CUFF	3794163, 3797111, 3801420, 3828141, 3831759, 3845036, 3852711, 3869824, 3869832, 3869838, 3890265, 3890268, 3890277, 3890280, 3890302, 3890304, 3894720, 3894721, 3897755, 3901173, 3901174, 3901178, 3904532, 3907902, 3907905, 3920905, 3935873, 3939393, 3940033, 3984935, 4002261, 4005761, 4021434, 4021435, 4026724, 4035848, 4035850, 4035855, 4039107, 4039910, 4056254, 4060255, 4063108, 4089228, 4089229, 4089231, 4089234, 4095955, 4105276, 4111669, 4113176, 4116141, 4119149, 4119150, 4122510, 4125924, 4128064, 4131045, 4131046, 4136171, 4139051, 4142498, 4142499, 4160012, 4160015, 4163879, 4176347, 4176348, 4178827, 4197659, 4221384, 4242055, 4244551, 4244552, 4257854, 4263224, 4263226, 4265146, 4265147, 4265149, 4265150, 4267578, 4279294, 4279295, 4283180, 4283183, 4291919, 4297028, 4299844, 4321558, 4321559, 4321560, 4331669, 4331670, 4335530, 4335531, 4357767, 4370605, 4371682, 4371683, 4371684, 4381795, 4381796, 4394645, 4396613
750160	AIRE-CUF TRACHY TUBE 6.0MM MID-RANGE	3790021, 3801381, 4021436, 4122498, 4156756

Part number	Description	Lot
750170	AIRE-CUF TRACHY TUBE 7.0MM MID-RANGE	4148043, 4151104, 4178829, 4185497, 4257859, 4283185, 4309561
750180	AIRE-CUF TRACHY TUBE 8.0MM MID-RANGE	3894702, 4046816, 4105325, 4119152, 4178830, 4185498, 4192842, 4233997, 4291924, 4371674, 4401163
60N025	NEONATAL TRACHEOSTOMY TUBE +	3853476, 3868313, 3952404, 3965318, 3991202, 4006287, 4006294, 4097838, 4125826, 4148013, 4185431, 4206833, 4221354, 4345039, 4348774, 4383653, 4400691
60N030	NEONATAL TRACH TUBE +	3877665, 4331629, 4381032, 4388201
60N035	NEONATAL TRACH TUBE +	3880712, 3904683, 4023792, 4056228, 4077083, 4107578, 4119113, 4180455, 4212789, 4279346, 4348780, 4348781
60N040	NEONATAL TRACH TUBE +	3868302, 3907990, 4015574, 4128033, 4176206, 4286814, 4345040, 4362872
60NFP30	NEONATAL TRACHEOSTOMY TUBE 3.0FLEXTEND PLUS	3868231
60NFP35	NEONATAL TRACHEOSTOMY TUBE 3.5FLEXTEND PLUS	4029505, 4033718, 4389891
60NFPS25	2.5MM UNCUFFED NEONATAL FLEXTEND PLUS TRACHEOSTOMY TUBE W/NEO STRAIGHT STRAP	3853440, 3874312, 3891526, 4327881
60NFPS30	3.0MM FLEXTEND NEO STRAIGHT TRACH TUBE	3853441, 3868206, 3877651, 3887742, 4168190, 4212773, 4276462
60NFPS35	3.5MM FLEXTEND NEO STRAIGHT TRACH TUBE	3853442, 3894902, 3918014, 3955767, 3988080, 3991149, 4011377, 4026689, 4041969, 4060203, 4063180, 4071966, 4083935, 4092635, 4119111, 4168147, 4206814, 4217441, 4223727, 4231494, 4260066, 4276463, 4327936, 4389894
60NFPS40	4.0MM FLEXTEND NEO STRAIGHT TRACH TUBE	3949020, 3991150, 3991151, 4005639, 4008215, 4060217, 4083917, 4091394, 4197613, 4204816, 4221341, 4231495, 4254240, 4276464, 4286801
60P025	PAED. TRACHEOSTOMY TUBE 2.5MM UNCUFFED	3880717, 3939666, 4156650, 4176238, 4209581, 4226268, 4254269, 4331631, 4335055, 4345041, 4374468, 4389923
60P030	PAED. TRACHEOSTOMY TUBE 3.0MM UNCUFFED	3936578, 3952364, 3952365, 3959293, 3997821, 4001215, 4011384, 4028385, 4040757, 4136145, 4159935, 4201393, 4216332, 4216333, 4217450, 4223738, 4254270, 4276478, 4335057, 4399210
60P035	PAED. TRACHEOSTOMY TUBE 3.5MM UNCUFFED	3840043, 3853480, 3853481, 3864261, 3868247, 3871069, 3877659, 3880688, 3901310, 3911424, 3920956, 3930014, 3939675, 3942522, 3952388, 3952389, 3952391, 3959310, 3982700, 3997822, 4001216, 4008230, 4015577, 4026684, 4034945, 4085993, 4095918, 4105252, 4110466, 4116092, 4128015, 4134012, 4134013, 4136146, 4139018, 4147997, 4201394, 4212790, 4221356, 4223739, 4237395, 4260076, 4273439, 4276479, 4283253, 4292179, 4322686, 4327946, 4331633, 4352799, 4382712, 4383654, 4388204, 4388206, 4389925, 4393424

Part number	Description	Lot
60P040	PAED. TRACHEOSTOMY TUBE 4.0MM UNCUFFED	3868274, 3952360, 3952362, 3962569, 3962571, 3988154, 4005678, 4011386, 4015578, 4029515, 4035761, 4051643, 4053701, 4077099, 4082681, 4086016, 4086017, 4095923, 4110467, 4113113, 4122444, 4130997, 4138995, 4142426, 4148005, 4217451, 4218717, 4226269, 4240164, 4273440, 4276480, 4279347, 4283254, 4283255, 4289497, 4292180, 4322687, 4335062, 4348797, 4351250, 4382715, 4383655
60P045	PAED. TRACHEOSTOMY TUBE 4.5MM UNCUFFED	3868289, 3897860, 3911428, 3911429, 3930056, 3942490, 3949024, 3952378, 3952380, 3982703, 3982705, 3988155, 3988156, 3988157, 4001218, 4005679, 4015582, 4018526, 4018527, 4029516, 4035764, 4051639, 4051640, 4060205, 4077069, 4077070, 4083907, 4086002, 4086003, 4092626, 4096837, 4119117, 4125816, 4130978, 4142422, 4168139, 4196295, 4206839, 4206840, 4209584, 4216334, 4218718, 4218719, 4226270, 4237397, 4240165, 4260077, 4273441, 4276481, 4283256, 4286818, 4292181, 4322688, 4331635, 4335069, 4374477, 4383656, 4388208, 4388209, 4389927
60P050	PAED. TRACHEOSTOMY TUBE 5.0MM UNCUFFED	3853485, 3871066, 3891527, 3904664, 3918022, 3942507, 3946271, 3952403, 3955781, 3988161, 3991205, 3997823, 4015583, 4015586, 4027994, 4027995, 4040759, 4077068, 4080313, 4085997, 4085998, 4092634, 4097839, 4107583, 4107584, 4113118, 4147981, 4168184, 4173735, 4204825, 4206843, 4209586, 4218721, 4221359, 4226271, 4233980, 4254280, 4283257, 4283258, 4286819, 4289496, 4292182, 4322689, 4380057, 4395804, 4400699
60P055	PAED. TRACHEOSTOMY TUBE 5.5MM UNCUFFED	3868223, 3897864, 3908004, 3908005, 3923725, 3939631, 3942495, 3982709, 3988162, 3991206, 4005683, 4015590, 4051649, 4066296, 4077092, 4083916, 4091395, 4105255, 4130992, 4142434, 4153620, 4201397, 4206844, 4209587, 4218722, 4223740, 4254281, 4254282, 4254283, 4273443, 4276483, 4286820, 4289499, 4292183, 4327941, 4327942, 4380059, 4383658, 4388213, 4389929, 4399217, 4399219
60PFP40	PAED. TRACHEOSTOMY TUBE 4.0MM FLEXTEND PLUS	3880719
60PFP540	4.0MM FLEXTEND PEDIATRIC PLUS STRAIGHT TRACH TUBE	3907983, 4196275, 4365800, 4395783
60PFP545	4.5MM FLEXTEND PEDIATRIC PLUS STRAIGHT TRACH TUBE	3877672, 4077109, 4180469, 4212778, 4223728, 4331608, 4348470
60PFP550	5.0MM FLEXTEND PEDIATRIC PLUS STRAIGHT TRACH TUBE	3877645, 4011378, 4331609, 4362851
60PFP560	6.0MM FLEXTEND PEDIATRIC PLUS STRAIGHT TRACH TUBE	3949022, 4026681, 4077088, 4091410, 4345010, 4374436, 4374437, 4399179, 4400667

Part number	Description	Lot
60PFS35	PAED. TRACHEOSTOMY TUBE 3.5MM STANDARD FLEXTEND PLUS	3853456, 3874294, 3991162, 4089301, 4206819, 4335011
60PFS40	PAED. TRACHEOSTOMY TUBE 4.0MM STANDARD FLEXTEND PLUS	3868310, 4260069, 4286803, 4379960, 4383631, 4389901
60PFS45	PAED. TRACHEOSTOMY TUBE 4.5MM STANDARD FLEXTEND PLUS	3843109, 3868224, 3884240, 3923717, 4018520, 4209568
60PFS50	PAED. TRACHEOSTOMY TUBE 5.0MM STANDARD FLEXTEND PLUS	3868297, 3868299, 3877642, 3884250, 3911431, 3939629, 3988108, 3991174, 3991176, 4051631, 4071969, 4083931, 4096826, 4122443, 4204819, 4212782, 4217446, 4218709, 4254252, 4279336, 4286805, 4289485, 4292173, 4335017, 4381023, 4388181, 4389904
60PFS55	PAED. TRACHEOSTOMY TUBE 5.5MM STANDARD FLEXTEND PLUS	3997818, 4033727, 4053735, 4122426, 4179360, 4209569, 4233969, 4276467, 4283244, 4322677, 4374449, 4383636, 4388182
60PFSS25	2.5MM PEDIATRIC UNCUFFED FLEXTEND PLUS TRACHEOSTOMY TUBE WITH NEONATE STRAIGHT NECKSTRAP	4086044
60PFSS30	3.0MM FLEXTEND PEDIATRIC STANDARD STRAIGHT TRACH TUBE	3962580, 4011380, 4077072, 4105256, 4119118, 4142421, 4156612, 4196281, 4201385, 4206823, 4212783, 4254255, 4260070, 4267849, 4273428, 4283245, 4399193
60PFSS35	3.5MM FLEXTEND PEDIATRIC STANDARD STRAIGHT TRACH TUBE	3868325, 3917978, 3926978, 3946233, 3946234, 3946237, 3959330, 3988118, 3997830, 4018523, 4026693, 4033731, 4035750, 4051627, 4053722, 4060207, 4071978, 4100880, 4113101, 4125810, 4138980, 4145703, 4147998, 4176218, 4197619, 4221349, 4223734, 4231509, 4233971, 4237387, 4240155, 4240157, 4254256, 4273429, 4276468, 4276470, 4322679, 4383642, 4388187
60PFSS40	4.0MM FLEXTEND PEDIATRIC STANDARD STRAIGHT TRACH TUBE TRACH TUBE	3853472, 3868237, 3868241, 3868243, 3884253, 3891514, 3988121, 3997833, 4001210, 4008223, 4015569, 4033733, 4035753, 4035754, 4053698, 4056232, 4066283, 4071982, 4071983, 4075239, 4075240, 4089303, 4092636, 4093739, 4097814, 4100885, 4110461, 4113110, 4119086, 4119087, 4125820, 4148004, 4153575, 4161979, 4168167, 4180450, 4204823, 4206828, 4209575, 4221351, 4221352, 4233972, 4237390, 4237391, 4237392, 4254261, 4254262, 4273434, 4273436, 4276472, 4276474, 4279340, 4286811, 4383645, 4388194, 4389917
60PFSS45	4.5MM FLEXTEND PEDIATRIC STANDARD STRAIGHT TRACH TUBE	3853473, 3868199, 3874305, 3904674, 3930027, 4015570, 4066293, 4071974, 4148015, 4185429, 4206830, 4216331, 4218713, 4231514, 4233975, 4240162, 4254264, 4260074, 4267857, 4267858, 4273437, 4347209, 4347210, 4388197, 4393420
60PFSS50	5.0MM FLEXTEND PEDIATRIC STANDARD STRAIGHT TRACH TUBE	3840057, 3911436, 3946241, 3946242, 3982696, 4035756, 4071975, 4145698, 4176234, 4218714, 4223737, 4267859, 4276477, 4383651

Part number	Description	Lot
60PFSS55	5.5MM FLEXTEND PEDIATRIC STANDARD STRAIGHT TRACH TUBE	4374465, 4388200
60SN025	2.5 UNCUFFED NEONATAL TRACHEOSTOMY TUBE	3868323, 3955794, 4089302, 4173737, 4327883, 4353056
60SN030	3.0 UNCUFFED NEONATAL TRACHEOSTOMY TUBE	4209588, 4286821, 4327917, 4348783, 4395805
60SN035	3.5 UNCUFFED NEONATAL TRACHEOSTOMY TUBE	3871055, 3897844, 3926955, 4023794, 4033738, 4086034, 4092629, 4107577, 4122445, 4134010, 4151017, 4168183, 4209589, 4221360, 4223742, 4254285, 4276484, 4322692, 4345044, 4348748, 4381038, 4389930
60SN040	4.0 UNCUFFED NEONATAL TRACHEOSTOMY TUBE	3861128, 3907976, 3952369, 4015601, 4026674, 4053715, 4091399, 4134020, 4151046, 4176211, 4233982, 4286822, 4292184, 4348789
60SP025	2.5 UNCUFFED PEDIATRIC TRACHEOSTOMY TUBE	3853490, 3894874, 4053702, 4168173, 4179371, 4204827, 4345045, 4365784
60SP030	3.0 UNCUFFED PEDIATRIC TRACHEOSTOMY TUBE	3853491, 3853492, 3877643, 3884256, 3894888, 3923735, 3952385, 3955780, 4001220, 4021423, 4051655, 4060225, 4077113, 4086024, 4116084, 4122451, 4139003, 4142430, 4153593, 4204828, 4209590, 4217452, 4388214, 4389931, 4395806
60SP035	3.5 UNCUFFED PEDIATRIC TRACHEOSTOMY TUBE	3840044, 3853493, 3853494, 3868228, 3868229, 3884268, 3897848, 3907968, 3926971, 3949027, 3952407, 3952408, 3965910, 3982712, 3988164, 3988165, 3991210, 4005685, 4012662, 4018528, 4026679, 4034946, 4034947, 4056229, 4066278, 4077085, 4083940, 4085994, 4095919, 4107587, 4110471, 4119115, 4130987, 4139019, 4145700, 4156660, 4161959, 4176210, 4233983, 4254288, 4276485, 4286824, 4292185, 4322693, 4322695, 4335088, 4351253, 4382710, 4388215, 4393428, 4393429
60SP040	4.0 UNCUFFED PEDIATRIC TRACHEOSTOMY TUBE	3868210, 3868211, 3868212, 3894897, 3897846, 3907967, 3946289, 3946290, 3948791, 3952338, 3952339, 3952340, 3955796, 3955797, 3988166, 3991211, 3997825, 4015603, 4015605, 4015606, 4026691, 4041966, 4051661, 4056239, 4063194, 4077066, 4083936, 4089288, 4092646, 4100889, 4107586, 4113097, 4122427, 4130975, 4134011, 4145678, 4151024, 4159987, 4171562, 4206848, 4218725, 4240169, 4254290, 4276486, 4289501, 4322696, 4322697, 4327952, 4348790, 4352806, 4369629, 4369630, 4374486, 4380061, 4389933
60SP045	4.5 UNCUFFED PEDIATRIC TRACHEOSTOMY TUBE	3840064, 3868194, 3887754, 3894901, 3897885, 3911439, 3930048, 3948793, 3952352, 3952353, 3955808, 3997826, 4001222, 4011387, 4015609, 4015610, 4035770, 4051647, 4066297, 4077080, 4080782, 4089290, 4095915, 4105247, 4113116, 4122452, 4130985, 4142432, 4147994, 4161995, 4197630, 4201400, 4283263, 4289502, 4345047,

Part number	Description	Lot
		4348794, 4357227, 4374487, 4388217, 4388218, 4399221
60SP050	5.0 UNCUFFED PEDIATRIC TRACHEOSTOMY TUBE	3840086, 3853498, 3868219, 3887748, 3897855, 3907970, 3949034, 3952382, 3997827, 4015611, 4015613, 4027992, 4027993, 4040760, 4053719, 4089299, 4100886, 4113120, 4134017, 4147983, 4156662, 4206849, 4218726, 4276488, 4279351, 4289503, 4322699, 4327950, 4335093, 4351255, 4352805, 4369627, 4380062, 4383663, 4388219, 4400710
60SP055	5.5 UNCUFFED PEDIATRIC TRACHEOSTOMY TUBE	3868322, 3901294, 3911430, 3952344, 3952345, 3982716, 3991214, 3991215, 4015615, 4051626, 4066279, 4092632, 4110472, 4134026, 4145711, 4161972, 4212797, 4233985, 4335094, 4351256, 4374489, 4374490, 4380063, 4399223
65N030	NEONATAL TRACHEOSTOMY TUBE +	3917999
65N035	NEONATAL TRACHEOSTOMY TUBE +	3871033, 4159985
65N040	NEONATAL TRACHEOSTOMY TUBE +	3871068, 4161958
65P025	PAED. TRACHEOSTOMY TUBE 2.5MM AIRE-CUF	3897888, 4016049
65P030	PAED. TRACHEOSTOMY TUBE 3.0MM AIRE-CUF	3904666, 3923718, 3926981, 4196257
65P035	PAED. TRACHEOSTOMY TUBE 3.5mm AIRE-CUF	3942487, 3955807, 4119112
65P040	PAED. TRACHEOSTOMY TUBE 4.0MM AIRE-CUF	4348385, 4383591
65P045	PAED. TRACHEOSTOMY TUBE 4.5MM AIRE-CUF	4089308, 4344346
65P050	PAED. TRACHEOSTOMY TUBE 5.0MM AIRE-CUF	3871030, 3930040, 4139011, 4163824, 4221325, 4328204, 4334867, 4369532, 4388090
65SN030	3.0MM AIRE-CUF NEONATAL TRACHEOSTOMY TUBE	4351231
65SN035	3.5MM AIRE-CUF NEONATAL TRACHE	3942499, 4348390
65SP035	3.5 AIRE-CUF PEDIATRIC TRACHEOSTOMY TUBE	4344966
65SP045	4.5 AIRE-CUF PEDIATRIC TRACHEOSTOMY TUBE	3997788
67N025	TTS NEONATAL TRACH TUBE +	3894899, 3949047, 4011355, 4139007, 4153599, 4185400, 4352755, 4372094, 4388097
67N030	TTS NEONATAL TRACH TUBE +	3868286, 4128032, 4148026, 4159991, 4185401, 4334878, 4348407, 4374401, 4380992, 4389867
67N035	TTS NEONATAL TRACH TUBE +	3868245, 3884266, 3923736, 3955773, 3961254, 3965335, 4016045, 4016046, 4156603, 4180470, 4328208, 4351233, 4362869, 4383593, 4395736
67N040	TTS NEONATAL TRACHY TUBE 4.0MMTIGHT TO SHAFT CUFF	3877658, 3901313, 3923737, 3936563, 3942521, 3965334, 4016051, 4331550, 4352757, 4362870
67NFPS25	NEONATAL TRACHEOSTOMY TUBE 2.5 TTS FLEXTEND STRAIGHT FLANGE	3853382, 3880680, 3901286, 3918017
67NFPS30	NEONATAL TRACHEOSTOMY TUBE 3.0 TTS FLEXTEND STRAIGHT FLANGE	3853383

Part number	Description	Lot
67NFPS35	NEONATAL TRACHEOSTOMY TUBE 3.5 TTS FLEXTEND STRAIGHT FLANGE	3853384, 3884238, 3904649, 3911417, 4018496, 4023777, 4035690, 4053705, 4097824, 4110431, 4125811, 4216300, 4237349, 4237350, 4260048, 4273412, 4276444, 4286788, 4389868
67NFPS40	NEONATAL TRACHEOSTOMY TUBE 4.0 TTS FLEXTEND STRAIGHT FLANGE	4026675, 4029493, 4148020, 4276445, 4362841, 4395743
67P030	TTS PEDIATRIC TRACH TUBE +	4334884, 4344971, 4374404, 4383597, 4388104, 4400626
67P035	TTS PEDIATRIC TRACH TUBE +	3981976, 3997797, 4011359, 4012663, 4026682, 4051652, 4063164, 4086022, 4095912, 4128030, 4136120, 4148011, 4156651, 4279319, 4286789, 4327931, 4334885, 4334886, 4362876, 4362878, 4369529, 4380069
67P040	TTS PEDIATRIC TRACH TUBE +	3853388, 3880696, 4033702, 4051617, 4056238, 4060202, 4083937, 4086033, 4097825, 4110433, 4110443, 4122425, 4136121, 4145676, 4161956, 4273415, 4286790, 4292155, 4327926, 4331562, 4334887, 4344973, 4352762, 4358514, 4362884, 4369541, 4388105, 4399130
67P045	TTS PEDIATRIC TRACH TUBE +	3897880, 3918004, 3923734, 3939664, 3946276, 3981983, 3997799, 3997800, 4035692, 4051653, 4063165, 4077112, 4091402, 4107574, 4131003, 4151016, 4159971, 4279320, 4328211, 4331563, 4334890, 4348413, 4353069, 4369547, 4369551, 4380070
67P050	TTS PEDIATRIC TRACH TUBE +	3853391, 3853392, 3887747, 3891533, 3901290, 3904665, 3917980, 3923719, 3949036, 3949037, 3949038, 3955793, 3959337, 3965923, 3991126, 4005585, 4018498, 4033703, 4053732, 4060210, 4077095, 4083915, 4107595, 4116096, 4142417, 4156614, 4179340, 4197604, 4286791, 4292156, 4322656, 4327925, 4331566, 4344974, 4344975, 4353078, 4369531, 4388107, 4395747
67P055	TTS PEDIATRIC TRACH TUBE +	4001126, 4005586, 4008199, 4018499, 4051630, 4063167, 4077082, 4083941, 4085996, 4092638, 4096831, 4105246, 4116086, 4119120, 4142454, 4156649, 4207454, 4286792, 4322657, 4327919, 4331567, 4374406, 4374407, 4380071, 4380072, 4383600, 4388108, 4388109, 4388110
67PFP40	PEDIATRIC TRACHEOSTOMY TUBE 4.0 TTS FLEXTEND PLUS V FLANGE	4348414
67PFP45	PEDIATRIC TRACHEOSTOMY TUBE 4.5 TTS FLEXTEND PLUS V FLANGE	4086000
67PFP55	PEDIATRIC TRACHEOSTOMY TUBE 5.5 TTS FLEXTEND PLUS V FLANGE	4035697
67PFP60	PEDIATRIC TRACHEOSTOMY TUBE 6.0 TTS FLEXTEND PLUS V FLANGE	3853395, 4331569, 4388112
67PFPS40	PEDIATRIC TRACHEOSTOMY TUBE 4.0 TTS FLEXTEND PLUS STRAIGHT FLANGE	3901306, 3926974
67PFPS45	PEDIATRIC TRACHEOSTOMY TUBE 4.5 TTS FLEXTEND PLUS STRAIGHT FLANGE	4035703, 4060204, 4096828, 4116110, 4153608, 4161964, 4240127

Part number	Description	Lot
67PFPS50	PEDIATRIC TRACHEOSTOMY TUBE 5.0 TTS FLEXTEND PLUS STRAIGHT FLANGE	4015529
67PFPS55	PEDIATRIC TRACHEOSTOMY TUBE 5.5 TTS FLEXTEND PLUS STRAIGHT FLANGE	4329835, 4344977, 4369560
67PFPS60	PEDIATRIC TRACHEOSTOMY TUBE 6.0 TTS FLEXTEND PLUS STRAIGHT FLANGE	3981989, 4380996
67PFS35	PEDIATRIC TRACHEOSTOMY TUBE 3.5 TTS FLEXTEND V NECK	3887715, 3923745, 4145702, 4328216
67PFS40	PEDIATRIC TRACHEOSTOMY TUBE 4.0 TTS FLEXTEND V NECK	3959325, 4015531, 4060221, 4119124, 4180476, 4221337, 4237360, 4254221, 4331573, 4357248, 4362850, 4388122, 4389876, 4395758
67PFSS30	PEDIATRIC TRACHEOSTOMY TUBE 3.0 TTS FLEXTEND STRAIGHT NECK	3853409, 3868326, 3877650, 3923723, 3931154, 3939668, 3981997, 4011365, 4051637, 4071984, 4075246, 4138990, 4329839, 4348422, 4357249, 4357250, 4374413
67PFSS35	PEDIATRIC TRACHEOSTOMY TUBE 3.5 TTS FLEXTEND STRAIGHT NECK	3858170, 3868263, 3868265, 3874323, 3880694, 3930046, 3939645, 3955809, 3959312, 4005605, 4008204, 4023783, 4041963, 4043943, 4063174, 4122428, 4128028, 4142455, 4148022, 4151058, 4196264, 4216314, 4217437, 4218699, 4237362, 4237363, 4237366, 4240132, 4254224, 4260060, 4267842, 4389881
67PFSS40	PEDIATRIC TRACHEOSTOMY TUBE 4.0 TTS FLEXTEND STRAIGHT NECK	3853417, 3868251, 3874298, 3874299, 3877664, 3884236, 3901281, 3901282, 4008205, 4011368, 4011370, 4026687, 4033713, 4033714, 4053706, 4056247, 4063175, 4077074, 4080796, 4086015, 4100891, 4107602, 4110440, 4113103, 4125812, 4142452, 4147986, 4151040, 4156626, 4196266, 4204807, 4212766, 4216316, 4231488, 4237369, 4237371, 4240135, 4254227, 4260061, 4267846, 4273421, 4276457, 4276458, 4279327, 4289473, 4322664, 4322665, 4389885, 4393401, 4399149
67PFSS45	PEDIATRIC TRACHEOSTOMY TUBE 4.5 TTS FLEXTEND STRAIGHT NECK	3939684, 3965912, 3982052, 4077076, 4096843, 4107605, 4110441, 4128040, 4204808, 4216318, 4233955, 4260063, 4279329, 4283231, 4283232, 4283233, 4322666, 4322667, 4327921, 4344989, 4380078, 4388140
67PFSS50	PEDIATRIC TRACHEOSTOMY TUBE 5.0 TTS FLEXTEND STRAIGHT NECK	3880686, 3894914, 3914573, 3930051, 3939654, 4011372, 4033716, 4035724, 4070850, 4142439, 4176241, 4233956, 4254229, 4267848, 4279332, 4289474, 4289475, 4292163, 4322668, 4329828, 4334219, 4344343, 4369582, 4383618, 4388142
67PFSS55	PEDIATRIC TRACHEOSTOMY TUBE 5.5 TTS FLEXTEND STRAIGHT NECK	3939678, 4018512, 4041964, 4096844, 4105260, 4130979, 4159957, 4171584, 4179351, 4260065, 4283235, 4327890, 4362866, 4383619, 4388144, 4389889, 4399156
67SN025	2.5 TTS CUFFED NEONATAL TRACHEOSTOMY TUBE	3897849, 3936582, 4016050, 4176209, 4328223, 4352775, 4365802
67SN030	3.0 TTS CUFFED NEONATAL TRACHEOSTOMY TUBE	3868317, 3877644, 3965330, 4185412, 4334959, 4348425, 4353070, 4374420, 4399158

Part number	Description	Lot
67SN035	3.5 TTS CUFFED NEONATAL TRACHEOSTOMY TUBE	3861151, 3887737, 3907993, 3923739, 3949041, 3965336, 4015535, 4016044, 4153588, 4237375, 4334960, 4348430, 4388146
67SN040	4.0 TTS CUFFED NEONATAL TRACHEOSTOMY TUBE	3861153, 3894898, 3923715, 3961255, 4016052, 4334961, 4365803
67SP025	2.5 TTS CUFFED PEDIATRIC TRACHEOSTOMY TUBE	3904678, 3961754, 4328227, 4334962, 4352776
67SP030	3.0 TTS CUFFED PEDIATRIC TRACHEOSTOMY TUBE	3877648, 3897883, 3931152, 3942489, 3955804, 3962574, 4075249, 4119088, 4201369, 4374423, 4388148, 4395775
67SP035	3.5 TTS CUFFED PEDIATRIC TRACHEOSTOMY TUBE	3894891, 3901311, 3926976, 3942450, 3942451, 3965920, 3982058, 3997809, 4012664, 4051662, 4066294, 4077067, 4086030, 4125830, 4147982, 4153606, 4240139, 4322669, 4327927, 4331584, 4348433, 4352779, 4362880, 4369585, 4369587, 4400655
67SP040	4.0 TTS CUFFED PEDIATRIC TRACHEOSTOMY TUBE	3853432, 3871054, 3880706, 3897862, 3907985, 3920947, 3926962, 3942485, 3952370, 3952371, 3987968, 3997810, 3997811, 4011374, 4021420, 4048008, 4053717, 4071971, 4075250, 4086005, 4095920, 4110443, 4125817, 4142423, 4148029, 4153614, 4159936, 4168140, 4328229, 4331586, 4348439, 4365804, 4380079
67SP045	4.5 TTS CUFFED PEDIATRIC TRACHEOSTOMY TUBE	3877649, 3887752, 3897884, 3908002, 3917995, 3946265, 4011375, 4029504, 4043932, 4051648, 4071973, 4075251, 4086029, 4110444, 4128011, 4151021, 4168143, 4237377, 4240140, 4286798, 4289478, 4328230, 4334966, 4344994, 4353071, 4365805, 4399161
67SP050	5.0 TTS CUFFED PEDIATRIC TRACHEOSTOMY TUBE	3853435, 3874295, 3891534, 3907988, 3920939, 3926982, 3942469, 3949040, 3959338, 3962595, 3982061, 3997813, 4026695, 4028710, 4077096, 4086009, 4100883, 4113099, 4125808, 4134025, 4142418, 4156617, 4161973, 4179352, 4286799, 4322670, 4328231, 4331588, 4334967, 4348454, 4348455, 4353081, 4353478, 4369588, 4388149
67SP055	5.5 TTS CUFFED PEDIATRIC TRACHEOSTOMY TUBE	3887753, 3894900, 3897882, 3911438, 3926963, 3941951, 3946266, 3949044, 3955803, 3965906, 3982062, 3997814, 4015536, 4026669, 4035727, 4048019, 4053736, 4077081, 4091409, 4100897, 4113117, 4125828, 4136136, 4145696, 4159989, 4163849, 4201372, 4231490, 4247291, 4289479, 4322671, 4328232, 4328233, 4374424, 4383620, 4388150, 4388151, 4395777, 4400657

URGENT MEDICAL DEVICE NOTIFICATION: RESPONSE FORM**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)**

24 MAY 2024

Check your inventory and complete the information below, even if you do not have the affected product.

Complete this form and return it to Sedgwick via fax at 1-855-566-7951 or email to smithsmedical3513@sedgwick.com. If you have questions about this form please call Sedgwick at 1-888-628-0731 (M-F, 8am-5pm ET).

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name and Title of Person Completing this Form	
Signature of Person Completing this Form	
Date	
If Purchased through a distributor, please list distributor name/location here for traceability purposes	

☐ **YES**, I have affected product, I have notified users in my facility, and I have followed the instructions provided to me to destroy all affected items. (Complete and return this form to Sedgwick via the fax/e-mail above). Please fill out the table below.☐ I have **NO** affected product (complete and return this form to Sedgwick via the fax/e-mail above)☐ Devices transferred/no longer owned; please indicate new owner contact information:

- Business Name: _____
- Address/City/Province/Postal Code: _____
- Contact Name: _____
- Contact Phone/E-mail Address: _____

• Have you distributed the product further to the retail level? ☐ **YES** ☐ **NO**

- If yes, have you notified your retail customers and asked them to contact Sedgwick at 1-888-628-0731 (M-F, 8am-5pm ET) to obtain a response form? **YES** ☐ **NO** ☐ (if no, explain below)

If you have distributed the product further, please provide the list of your retail customers, inclusive of customer name, address, city, province, postal code, telephone number and quantity of product distributed along with your completed response form to the contact information listed above so Smiths Medical can verify effectiveness of the recall notification to the appropriate level.

Adverse events and complaints associated with the use of these products should be reported and emailed to Smiths Medical's Global Complaint Management Department (canadacomplaints@icumed.com).

Lot Number	Quantity in inventory	Quantity to be Destroyed	Date of Destruction	Wholesaler/Distributor Name If you purchased from Wholesalers/Distributors include name, address, city, province, postal code, quantity from each, and invoice number. If you purchased directly from Smiths Medical leave this section blank.	PO #	Invoice #	Debit Memo #
				1			
				2			
				3			

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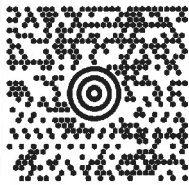
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INDIANAPOLIS IN 46241

SHP#: A0Y7 7
SHP WT: LETTER
DATE: 24 MAY 2024

DEAR VALUED CUSTOMERS

SHIP (403) 342-6330
TO: MEDIGAS LIMITED
127 - 3016 10TH AVE NE

CALGARY AB T2A6A3



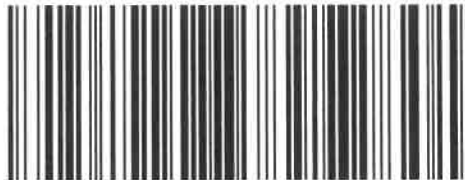
CAN 743 9-01



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TRACKING: 1Z A0Y 770 66 2499 2166

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