

URGENT - FIELD SAFETY NOTICE

Type of Action:			Recall		
Reference:			40004925		
Commercial Name	Material	Batch	Commercial Name	Material	Batch
ADAPTOR,040 HUM,INTL	400040	Refer to Appendix 2	AQUAPAK 640 SW,650 ML W/040 ADAPTOR	006-40	Refer to Appendix 2
AQUA 540 SW, 540 W/ 040 ADAPTOR	005-40		AQUAPAK 640 SW,650 ML W/040 ADAPTOR,FREN	006-40F	
AQUAPAK 101 SW,190 ML W/040 ADAPTOR,JAPA	001-40J			006-40J	
AQUAPAK 340 SW,340 ML W/040 ADAPTOR	003-40		AQUAPAK 640 SW,650 ML W/040 ADAPTOR,INTL	400640	
AQUAPAK 340 SW,340 ML W/040 ADAPTOR,FREN	003-40F		AQUAPAK SW/EAU STERILE,340 ML W/ADAPTOR	003-40C	
AQUAPAK 340 SW,340 ML W/040 ADAPTOR,INTL	400340		AQUAPAK SW/EAU STERILE,650 ML W/ADAPTOR	006-40C	
AQUAPAK 340 SW,340 ML W/040 ADAPTOR,JAPA	003-40J		HUMIDIFIER ADAPTOR 040	000-40	
AQUAPAK 340 SW,340 ML W/040B ADAPTOR,BRI	003-40B				

Dear Customer,

Details of affected devices

Teleflex has initiated a voluntary Field Safety Corrective Action for the above listed products.

Description of the problem

Teleflex Medical is recalling the products referenced above due to a possibility that the packages may contain foreign material, (predominantly synthetically derived PVC). This foreign matter has only been found in the package and not in the gas flow path of the humidifier product. It is unlikely that the foreign matter particles can migrate into the sterile water reservoir, they are unlikely to leave the reservoir or enter the connecting tubing between the reservoir and the patient. The hazard of mild lung discomfort, which is usually temporary and reversible would only occur if the small foreign matter migrated from the package to the reservoir and reached the patient airway by migrating from the reservoir to the connecting tubing at very high gas flows. In this scenario, the natural human defences to keep airways free and clear including the physical actions of the epiglottis and arytenoid cartilages in blocking the airway would also have to be overcome. Teleflex Medical is recalling these products in an effort to provide our customers and their patients with the highest quality product possible.

FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS:

ADVICE ON ACTION TO BE TAKEN BY MEDICAL STAFF

Please note:

Only the 040 Humidifier adaptor packaged with the water bottle is affected by this recall and should be returned to Teleflex Medical. The water bottle is **not** affected by this recall. If you have product affected by this recall, open the carton of product and remove the 040 humidifier adaptors to return the adaptors only to Teleflex Medical, as shown in the pictures below.



1. We request that you check your inventory for product within the scope of this field action. Users should cease use and distribution of stock of the affected product batch and quarantine immediately.
2. If you do not have stock in scope of this field action as referred to in above table then mark the according checkbox on the Acknowledgement form (Appendix 1) and return the form to the fax number or e-Mail-address mentioned below.
3. If you have stock from the affected product as referred to in above table, mark the according checkbox on the Acknowledgement form (Appendix 1). Contact customer service by calling the phone number mentioned in Section 6 who will issue you with a return number. Write this return number into the respective field in the Acknowledgement form.
4. Complete 'Appendix 1' for all products in your possession and under control. Return this form immediately to Customer Service.
5. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.

INSTRUCTION FOR DISTRIBUTORS OF AFFECTED PRODUCT

1. If you are a distributor, provide this field safety notice to all of your customers who have received product in scope of this Field Action. Your customer is then required to complete the acknowledgement form and return this to you.

2. As a Distributor you are required to confirm to Teleflex that you have completed the field activity outlined above. Upon completion of your actions, please forward the completed Acknowledgement Form to Customer Service.
3. Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which Teleflex distribute directly will be notified by Teleflex.
4. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TK area, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex.

1. Teleflex

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

2. Transmission of this Field Safety Notice

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

Maintain awareness of this notice until all required actions have been completed in your organisation

3. Contact reference person

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

Customer Service:

Contact: Herr Horst Erbe Telephone: 07151 / 406 – 431
Fax: +49 7151 / 406-566 e-mail: horst.erbe@teleflex.com

Please be advised that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities to which Teleflex distribute directly will be notified by Teleflex.

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

For and on behalf of Teleflex,

██████████

██████████
VP, Global QARA

Appendix 1

Customer No: _____

FIELD SAFETY CORRECTIVE ACTION
Teleflex Ref. 40004925

Acknowledgement Form

URGENT ATTENTION REQUIRED

Return completed form immediately to:

FAX: +49 7151 / 406-566

E-mail : horst.erbe@teleflex.com

Please check applicable box:

<input type="checkbox"/> We confirm receipt of this FSN and completed the required actions contained therein. We confirm that our inventory does NOT include products affected by this Field Action.	<input type="checkbox"/> We confirm receipt of this FSN and completed the required actions contained therein. We confirm our inventory DOES include products affected by this Field Action. The use and further distribution of the affected products has been stopped. All products are on hold and the quantity stated below will be returned.
	<div style="border: 1px solid red; padding: 5px; display: inline-block;">Return Authorisation No _____</div>

Please CLEARLY print the below return information:

Name of Affected Products:	Adaptor – Foreign Material – Jan 2015		
Product Number	(Size)	Lot Number	Quantity (Returning)

Return Instructions:

- Please label product returns as "Field Action Returns".
 - Include a copy of this form (including RAN Number) with product returns.
- Returns excluding ALL necessary documentation CANNOT be processed.

Institution Name - (Hospital, Health Care Organisation, etc.)	
Institution Address:	Email Address:
	Phone Number:
Form completed by:	
Print Name :	Institution Stamp:
Signature :	
Date:	

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Product	Lot	Product	Lot	Product	Lot	Product	Lot	Product	Lot	Product	Lot	Product	Lot
400340	001147		072137		122137		174137		232147		281137		349147
400640	002146		073137		123137		174147		233137		282137		350147
000-40	BE08		074147		123147		175137		234147		283137		351137
	BG05		075137		124137		175147		235137		284137		352137
	BG08		075147		125137		176137		236147		285147		354137
	BM18		077137		126137		176147		237137		286147		355137
	CB11		079147		126147		177137		237147		287147		356147
	CB17		080147		127137		177147		238147		288147		358137
001-40J	001139		081147		128137		178137		239137		289137		359137
	003139		082137		129137		178147		239147		289147		359147
003-40	004147		083137		129147		179147		240147		290147		361137
	016147		083147		130147		180147		241147		291147		361147
	018147		084147		131137		181147		242147		292137		363137
	020147		085137		131147		182147		243147		293147		364137
	028147		085147		132137		183147		244147		294137		364147
	031147		086137		133137		184147		245137		295147		365147
	034147		087137		133147		185147		245147		296147		367137
	037147		087147		134137		188137		246147		298147		368137
	038137		088137		134147		190137		247137		300147		368147
	039137		088147		135137		192137		247147		302147		369137
	040137		089137		135147		195137		248147		303147		370137
	040147		089147		136137		198137		249147		304137		371137
	041137		090137		137137		201137		250137		304147		371147
	042137		090147		137147		204137		250147		306137		372137
	043137		092147		138137		204147		251137		306147		373137
	043147		093137		138147		205137		252137		308137		373147
	044137		094147		139137		206137		253137		308147		374137
	045137		095137		139147		207147		254137		309147		374147
	046137		095147		140137		208147		255137		310147		375137
	047137	003-40	096137	003-40	141137	003-40	209137	003-40	255147	003-40	311147	003-40	376137
	048137		096147		142137		209147		256137		312147		376147
	048147		097137		143137		210147		257137		314147		377137
	049137		097147		144147		211137		257147		315137		377147
	050137		098137		147147		211147		258137		315147		378137
	050147		098147		148137		212147		260147		317147		379137
	051137		099137		150137		213147		261147		318137		379147
	051147		100137		150147		214137		262137		319137		380137
	052137		101137		152137		214147		263147		319147		381137
	052147		102137		153147		215147		264147		320137		381147
	054137		105137		154137		216147		265137		321137		382147
	054147		106137		154147		217137		266147		322137		383147
	055137		106147		155147		217147		268137		323137		384147
	055147		107147		156147		218137		268147		324147		386147
	056137		108137		157137		218147		269137		328147		387147
	056147		109137		157147		219137		270147		331147		388147
	058137		110137		158137		219147		271137		333147		390147
	058147		110147		158147		220147		271147		336147		392147
	059147		111137		159147		221137		272137		337147		393147
	060137		112137		160137		221147		272147		338147		394147
	060147		113137		162137		222137		273137		339147		395147
	061147		113147		164137		222147		273147		340147		396147
	062137		114137		166137		223147		274137		341137		397147
063147		115137		167137		224137		274147		341147		398147	
064137		116137		168137		224147		275137		342147		399147	
064147		117137		169137		225147		275147		343147		400147	
067137		118137		170137		226137		276137		344147		401147	
068137		119137		171137		226147		277137		345137		402147	
070147		119147		172137		228137		278137		345147		403147	
071137		120137		172147		229147		279137		348137		404147	
071147		121137		173137		230137		280137		348147		405137	

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Product	Lot	Product	Lot	Product	Lot	Product	Lot	Product	Lot	Product	Lot	Product	Lot
	405147		530137		643137		073147		489147		329137		022135
	406147		532137		644137		077147		490147		332137		023135
	407147		534137		646137		091147		494147		335137		025135
	408137		537137	003-40	648137		093147		496137		337137		026135
	415137		538137		649137		117147		505147		398137		027135
	418137		540137		651137		120147		506147		400137		028135
	421137		541137		652137		121147		508137		401137	005-40	029135
	428137		543137		312137		188147		511137		403137		030135
	430137		544137		394137		192147		519137		406137		031135
	431137		547137	003-40B	396137		195147		521137		409137		032135
	432137		548137		429137		198147		525137		412137		033135
	433137		550137		542147		201147	003-40F	535137		417137		034135
	434137		552137		674147		227147		539137		419137		035135
	435137		555137		021147		233147		542137	003-40J	422137		036135
	438137		557137		067147		238137		562137		427137		021146
	439137		559137		099147		242137		565137		437137		022146
	440137		561137		124147		251147		584137		486137		024136
	441137		564137		127147		254147		587137		487137		025136
	442137		567137		144137		258147		589137		490137		026136
	442147		571137		173147		260137		591137		492137		028136
	443137		573137		187137		264137		595137		528137		030136
	444137		574137		193137		267137		598137		566137		033136
	445137		576137		210137		276147		601137		570137		034136
	445147		577137		230147		277147		015147		613137		038146
	446137		579137		249137		285137		017147		616137		041136
	447137		581137		280147		288137		019147		619137		042136
	448137		583137		295137		291137		105147		624137		042146
	449137		585137		296137		292147		109147		627137		043136
	450137		586137		307147		298137		111147		001135		043146
003-40	452137	003-40	588137	003-40C	324137	003-40F	301137		115147				044136
	453137		593137		346147		302137		118147		001145		044146
	454137		596137		354147		310137		130137		002135		045136
	455137		599137		355147		314137		140147		002145		045146
	456137		600137		357147		325137		141147		003135		046136
	457137		602137		410147		327137		142147		003145		047136
	458137		603137		411137		330137		143147		004135		049146
	459137		604137		414137		333137		146147		004145	006-40	050146
	460137		605137		415147		339137		149147		005135		051146
	461137		606137		451137		344137		151147		005145		053136
	482137		607137		473137		347137		152147		006135		058136
	484137		608137		504137		350137		160147		006145		059136
	493137		609137		536137		357137	003-40J	161147		007135		060146
	495137		610137		553137		360137		162147		007145		061136
	497137		617137		592137		382137		163147	005-40	008135		061146
	498137		620137		612137		384137		164147		008145		063136
	499137		621137		615137		386137		165147		009135		064136
	500137		622137		002147		388137		166147		009145		064146
	501137		623137		005147		393137		168147		010135		065136
	503137		625137		007147		395137		169147		010145		065146
	506137		626137		009147		399137		170147		011135		066136
	507137		628137		011147		402137		171147		012135		066146
	510137		629137		014147		404137		180137		013135		067136
	513137		630137	003-40F	045147		459147		181137		014135		067146
	514137		631137		046147		462137		184137		015135		071136
	515137		632137		049147		462147		185137		016135		072136
	517137		633137		053147		464137		212137		017135		073136
	520137		635137		057147		466137		240137		018135		096136
	522137		639137		062147		468137		241137		019135		097136
	526137		640137		066147		480147		244137		020135		098136
	529137		642137		068147		482147		326137		021135		099136

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Product	Lot	Product	Lot	Product	Lot	Product	Lot	Product	Lot	Product	Lot	Product	Lot
006-40	100136	006-40F	056146	400340	101147	400340	235147	400340	410137	400340	641137	400640	084136
	101136		102136		102147		236137		413137		645137		085136
	119136		103146		103137		243137		416137		647137		086136
	124136		110136		103147		246137		420137		650137		088136
	125136		115136		104137		248137		424137		003146		089136
	131136		132136		104147		252147		425137		004146		090136
	135136		147136		107137		253147		426137		005146		091136
	136136		153136		114147		256147		463137		006146		092136
	137136		159136		116147		259137		465137		009146		093136
	138136		165136		122147		259147		467137		010146		094136
	139136		006-40J		007146		125147		261137		469137		011146
	144136	028146			128147	262147	470137	012146	105136				
	145136	029146			132147	263137	471137	016146	106136				
	150136	033146			136147	266137	472137	017146	107136				
	151136	034146			145137	270137	474137	018136	108136				
	152136	068136			147137	278147	475137	018146	109136				
	154136	075136			149137	279147	476137	019136	116136				
	155136	083136			151137	281147	477137	019146	117136				
	156136	103136			153137	282147	478137	020136	118136				
	157136	111136			155137	283147	479137	021136	121136				
	172136	112136			156137	284147	480137	022136	122136				
	173136	113136	159137		286137	481137	024146	123136					
	176136	114136	161137		287137	483137	025146	128136					
	177136	126136	163137		290137	485137	026146	129136					
	181136	146136	165137		293137	488137	030146	130136					
	182136	400040	BE15		179137	297137	489137	031146	133136				
	183136		BM17		182137	297147	491137	032146	134136				
	184136	400340	006147		183137	299137	494137	035146	140136				
	185136		008147		186137	299147	502137	036146	141136				
	186136		010147		186147	300137	505137	037146	142136				
	188136		012147		189137	301147	509137	039136	143136				
	189136		013147		189147	303137	512137	041146	148136				
	190136		022147		190147	305137	516137	046146	149136				
191136	023147		191137	305147	518137	047146	158136						
192136	024147		191147	307137	523137	048146	160136						
196136	025147		193147	309137	524137	049136	161136						
197136	026147		194137	313137	527137	050136	162136						
198136	027147		194147	313147	531137	051136	163136						
006-40C	013146	400340	029147	400340	196147	400340	316137	400640	533137	400640	052136	400640	164136
	020146		030147		197137		328137		545137		053146		166136
	029136		032147		197147		331137		549137		054136		167136
	035136		033147		200137		334137		551137		054146		168136
	039146		035147		200147		336137		554137		055136		169136
	040136		036147		202147		338137		556137		055146		170136
	048136		038147		203137		343137		558137		056136		174136
	060136		039147		203147		346137		560137		057136		175136
	062136		041147		205147		349137		563137		057146		179136
	074136		042147		206147		353137		568137		058146		180136
	083146		044147		207137		356137		569137		059146		193136
	087136		047147		208137		362137		572137		062146		194136
	104136		057137		213137		365137		575137		063146		195136
	171136		059137		216137		366137		578137		068146		
	178136		061137		220137		383137		580137		069136		
006-40F	001146	400340	072147	400340	223137	400340	385137	400340	582137	400340	069146	400340	
	008146		076147		225137		387137		590137		070136		
	014146		078147		227137		389137		594137		077136		
	015146		080137		228147		390137		597137		078136		
	023146		082147		229137		391137		611137		079136		
	040146		086147		231147		392137		614137		080136		
	052146		100147		234137		407137		618137		082136		