

16 April 2014

URGENT - FIELD SAFETY NOTICE

TYPE OF ACTION:	Recall	
TELEFLEX REFERENCE:	40003628	
PRODUCT	PART #	LOT
040 Humidifier Adaptor, Shelfpak	400040	Ref Appendix 2
AquaPak 340 Sterile Water, 340ml w/040 Adaptor	400340	
AquaPak 640 Sterile Water, 650ml w/040 Adaptor	400640	
Humidifier Adaptor 040	000-40	
Humidifier Adaptor 040 Shelfpak, French	000-40F	
AquaPak Kit, 190ml Sterile Water w/000-40 Humidifier Adaptor, Japanese	001-40J	
AquaPak 340 Sterile Water, 340ml w/040 Adaptor	003-40	
AquaPak SW/EAU Sterile, 340ml w/Adaptor	003-40C	
AquaPak 340 Sterile Water, 340ml w/040 Adaptor, French	003-40F	
AquaPak 340 Sterile Water, 340ml w/040 Adaptor, Japanese	003-40J	
AquaPak 540 Sterile Water, 540ml w/040 Adaptor	005-40	
AquaPak 640 Sterile Water, 650ml w/040 Adaptor	006-40	
AquaPak SW/EAU Sterile, 650ml w/Adaptor	006-40C	
AquaPak 640 Sterile Water, 650ml w/040 Adaptor, French	006-40F	
AquaPak 640 Sterile Water, 650ml w/040 Adaptor, Japanese	006-40J	
040 Humidifier Adaptor, Shelfpak	400040	

Dear Customer,

1. Details of affected devices

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

2. Description of the problem

Teleflex Medical has issued a voluntary recall for the above listed products due to the possibility that the seals may be creased which may potentially affect seal integrity. This defect is not likely to cause adverse health consequences, as the adaptors are used as part of a non-sterile system. Teleflex Medical is recalling these products in an effort to provide our customers and their patients with the highest quality product possible.

3. FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS:

ADVICE ON ACTION TO BE TAKEN BY MEDICAL STAFF

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 affected product 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 there.
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.

4. Teleflex

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

5. Transmission of this Field Safety Notice

This notice should be passed on 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

6. Contact reference person

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

Customer Service: Contact: Shane Kenny
FAX: +353 (0)1 4370773

Telephone: +353 (0)90 6460869
E-mail: Recalls.intl@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,

[Redacted Signature]

[Redacted Name]
Senior Director of Quality International.

FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX - IMMEDIATE ATTENTION REQUIRED

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +353 (0)1 4370773

E-mail: Recalls.intl@teleflex.com

<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 is stopped. All products are put on hold and the amount below will be returned. Return Authorisation No _____
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PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY.

COMMERCIAL NAME OF AFFECTED PRODUCTS:	AquaPak / Humidifier Adaptor	
PRODUCT NUMBER	LOT NUMBER	QUANTITY
<ul style="list-style-type: none"> Include a copy of the completed Acknowledgement Form in the returns package with the returned units Ensure the RAN number is clearly visible on the returns package. Please label returns as "Field Action Returns" 		

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

INSTITUTION NAME (EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSTITUTION ADDRESS	Phone / Fax
FORM COMPLETED BY:	TITLE/ROLE
PRINT NAME: _____	
SIGNATURE: _____	
DATE	

Appendix 2

Part #	Lot #	Part #	Lot #	Part #	Lot #	Part #	Lot #	Part #	Lot #	Part #	Lot #	Part #	Lot #	Part #	Lot #	Part #	Lot #	Part #	Lot #
400340	082127	400340	228127	400340	345127	400340	481127	400640	060126	400640	127126	003-40	126127	003-40	168127	003-40	206127	003-40	285127
400340	085127	400340	230127	400340	350127	400340	483127	400640	061126	400640	151126	003-40	127127	003-40	169127	003-40	208127	003-40	286127
400340	088127	400340	232127	400340	353127	400340	486127	400640	066126	001-40J	001129	003-40	128127	003-40	170127	003-40	210127	003-40	294127
400340	092127	400340	239127	400340	356127	400340	487127	400640	067126	001-40J	002129	003-40	129127	003-40	171127	003-40	212127	003-40	295127
400340	094127	400340	241127	400340	359127	400340	489127	400640	072126	003-40	088137	003-40	130127	003-40	172127	003-40	214127	003-40	296127
400340	097127	400340	243127	400340	386127	400340	491127	400640	073126	003-40	093127	003-40	131127	003-40	173127	003-40	216127	003-40	297127
400340	100127	400340	245127	400340	388127	400340	493127	400640	074126	003-40	095127	003-40	132127	003-40	175127	003-40	218127	003-40	298127
400340	102127	400340	246127	400340	390127	400340	496127	400640	081126	003-40	096127	003-40	133127	003-40	176127	003-40	219127	003-40	299127
400340	104127	400340	248127	400340	392127	400340	516127	400640	082126	003-40	098127	003-40	134127	003-40	178127	003-40	220127	003-40	301127
400340	106127	400340	250127	400340	395127	400340	577127	400640	083126	003-40	099127	003-40	135127	003-40	179127	003-40	221127	003-40	302127
400340	108127	400340	252127	400340	399127	400340	580127	400640	084126	003-40	101127	003-40	136127	003-40	180127	003-40	234127	003-40	303127
400340	137127	400340	256127	400340	403127	400640	021126	400640	085126	003-40	103127	003-40	138127	003-40	182127	003-40	235127	003-40	305127
400340	141127	400340	259127	400340	406127	400640	022126	400640	093126	003-40	105127	003-40	140127	003-40	183127	003-40	237127	003-40	306127
400340	145127	400340	263127	400340	410127	400640	030126	400640	094126	003-40	107127	003-40	143127	003-40	185127	003-40	240127	003-40	308127
400340	148127	400340	266127	400340	414127	400640	031126	400640	095126	003-40	111127	003-40	144127	003-40	186127	003-40	242127	003-40	310127
400340	154127	400340	269127	400340	419127	400640	032126	400640	096126	003-40	112127	003-40	146127	003-40	187127	003-40	258127	003-40	311127
400340	156127	400340	289127	400340	421127	400640	033126	400640	100126	003-40	113127	003-40	147127	003-40	188127	003-40	262127	003-40	319127
400340	159127	400340	290127	400340	430127	400640	034126	400640	101126	003-40	114127	003-40	149127	003-40	189127	003-40	265127	003-40	321127
400340	161127	400340	292127	400340	432127	400640	037126	400640	102126	003-40	115127	003-40	150127	003-40	190127	003-40	268127	003-40	323127
400340	163127	400340	307127	400340	447127	400640	038126	400640	103126	003-40	116127	003-40	151127	003-40	191127	003-40	271127	003-40	324127
400340	194127	400340	309127	400340	450127	400640	039126	400640	104126	003-40	117127	003-40	152127	003-40	192127	003-40	273127	003-40	325127
400340	198127	400340	312127	400340	453127	400640	040126	400640	109126	003-40	118127	003-40	153127	003-40	193127	003-40	275127	003-40	326127
400340	200127	400340	314127	400340	456127	400640	047126	400640	110126	003-40	119127	003-40	158127	003-40	196127	003-40	278127	003-40	327127
400340	204127	400340	316127	400340	459127	400640	048126	400640	116126	003-40	120127	003-40	160127	003-40	197127	003-40	279127	003-40	328127
400340	207127	400340	318127	400340	462127	400640	049126	400640	117126	003-40	121127	003-40	162127	003-40	199127	003-40	280127	003-40	329127
400340	209127	400340	320127	400340	465127	400640	050126	400640	118126	003-40	122127	003-40	164127	003-40	201127	003-40	281127	003-40	330127
400340	223127	400340	322127	400340	467127	400640	051126	400640	119126	003-40	123127	003-40	165127	003-40	202127	003-40	282127	003-40	331127
400340	224127	400340	338127	400340	477127	400640	052126	400640	125126	003-40	124127	003-40	166127	003-40	203127	003-40	283127	003-40	332127
400340	226127	400340	340127	400340	478127	400640	059126	400640	126126	003-40	125127	003-40	167127	003-40	205127	003-40	284127	003-40	342127

Part #	Lot #	Part #	Lot #	Part #	Lot #	Part #	Lot #	Part #	Lot #	Part #	Lot #	Part #	Lot #	Part #	Lot #	Part #	Lot #	Part #	Lot #
003-40	344127	003-40	409127	003-40	482127	003-40C	497127	003-40F	251127	003-40F	398127	003-40J	291127	005-40	010125	006-40	070126	006-40F	080126
003-40	346127	003-40	411127	003-40	484127	003-40C	500127	003-40F	253127	003-40F	401127	003-40J	293127	005-40	011125	006-40	075126	006-40F	092126
003-40	348127	003-40	412127	003-40	494127	003-40F	046127	003-40F	257127	003-40F	405127	003-40J	363127	005-40	012125	006-40	077126	006-40F	107126
003-40	349127	003-40	416127	003-40	498127	003-40F	049127	003-40F	260127	003-40F	433127	003-40J	364127	005-40	013125	006-40	078126	006-40F	108126
003-40	351127	003-40	418127	003-40	499127	003-40F	052127	003-40F	261127	003-40F	435127	003-40J	365127	005-40	014125	006-40	079126	006-40F	115126
003-40	352127	003-40	420127	003-40	501127	003-40F	053127	003-40F	264127	003-40F	438127	003-40J	366127	005-40	015125	006-40	086126	006-40J	028126
003-40	354127	003-40	439127	003-40	502127	003-40F	055127	003-40F	267127	003-40F	464127	003-40J	367127	005-40	016125	006-40	087126	006-40J	035126
003-40	355127	003-40	440127	003-40	503127	003-40F	056127	003-40F	270127	003-40F	466127	003-40J	385127	005-40	017125	006-40	088126	006-40J	045126
003-40	357127	003-40	441127	003-40	504127	003-40F	058127	003-40F	272127	003-40F	468127	003-40J	387127	005-40	019125	006-40	089126	006-40J	063126
003-40	358127	003-40	442127	003-40	505127	003-40F	059127	003-40F	274127	003-40F	470127	003-40J	389127	005-40	020125	006-40	090126	006-40J	098126
003-40	360127	003-40	443127	003-40	506127	003-40F	061127	003-40F	276127	003-40F	471127	003-40J	391127	005-40	021125	006-40	097126	006-40J	105126
003-40	361127	003-40	444127	003-40	507127	003-40F	062127	003-40F	288127	003-40F	473127	003-40J	393127	005-40	022125	006-40	111126	006-40J	106126
003-40	369127	003-40	446127	003-40	508127	003-40F	065127	003-40F	300127	003-40F	474127	003-40J	423127	005-40	023125	006-40	120126	000-40	AA19
003-40	370127	003-40	448127	003-40	510127	003-40F	066127	003-40F	304127	003-40F	485127	003-40J	424127	005-40	024125	006-40	121126	000-40	AB12
003-40	372127	003-40	449127	003-40	546127	003-40F	068127	003-40F	313127	003-40F	488127	003-40J	429127	005-40	025125	006-40	122126	000-40	AC20
003-40	373127	003-40	451127	003-40	547127	003-40F	069127	003-40F	315127	003-40F	490127	003-40J	431127	005-40	026125	006-40	123126	000-40	AE03
003-40	374127	003-40	452127	003-40	548127	003-40F	071127	003-40F	317127	003-40F	492127	003-40J	434127	005-40	032125	006-40	128126	000-40	AE18
003-40	375127	003-40	454127	003-40C	109127	003-40F	072127	003-40F	333127	003-40F	495127	003-40J	436127	006-40	041126	006-40	155126	000-40	AE21
003-40	377127	003-40	455127	003-40C	155127	003-40F	074127	003-40F	334127	003-40F	513127	003-40J	437127	006-40	042126	006-40	156126	000-40	AF09
003-40	378127	003-40	457127	003-40C	157127	003-40F	211127	003-40F	336127	003-40F	518127	003-40J	445127	006-40	043126	006-40C	029126	000-40	AF16
003-40	380127	003-40	460127	003-40C	174127	003-40F	213127	003-40F	339127	003-40J	177127	005-40	001125	006-40	044126	006-40C	036126	000-40	AG10
003-40	381127	003-40	461127	003-40C	195127	003-40F	215127	003-40F	341127	003-40J	181127	005-40	002125	006-40	053126	006-40C	065126	000-40	AG12
003-40	383127	003-40	463127	003-40C	222127	003-40F	217127	003-40F	343127	003-40J	184127	005-40	003125	006-40	054126	006-40C	071126	000-40	AH11
003-40	394127	003-40	469127	003-40C	277127	003-40F	233127	003-40F	368127	003-40J	225127	005-40	004125	006-40	055126	006-40C	076126	000-40F	AA05
003-40	397127	003-40	472127	003-40C	335127	003-40F	236127	003-40F	371127	003-40J	227127	005-40	005125	006-40	056126	006-40C	091126	000-40F	AC01
003-40	400127	003-40	475127	003-40C	337127	003-40F	238127	003-40F	376127	003-40J	229127	005-40	006125	006-40	057126	006-40F	020126	400040	AG14
003-40	402127	003-40	476127	003-40C	384127	003-40F	244127	003-40F	379127	003-40J	231127	005-40	007125	006-40	058126	006-40F	046126		
003-40	407127	003-40	479127	003-40C	422127	003-40F	247127	003-40F	382127	003-40J	254127	005-40	008125	006-40	068126	006-40F	062126		
003-40	408127	003-40	480127	003-40C	425127	003-40F	249127	003-40F	396127	003-40J	287127	005-40	009125	006-40	069126	006-40F	064126		