

URGENT MEDICAL DEVICE RECALL NOTIFICATION

Thursday, January 22, 2015

Dear Valued Life-Assist Customer,

According to our records you have purchased an item that has been recalled by the manufacturer. Please examine your stock to determine if you have any of the affected lot numbers (attached) in your possession.

Life-Assist No.	Manufacturer No.	Product Description	Lot #s
OH0340	003-40	Aquapak® Humidifier, Pre-filled, 340 mL	See attached
OH0640	006-40	Aquapak® Humidifier, Pre-filled, 650 mL	See attached

Teleflex Medical has issued a voluntary recall for certain lot numbers of the humidifier adaptors included in the product codes listed above. Please see the attachment for affected lot numbers.

Reason for Recall: Teleflex Medical has issued this recall due to the possibility that the packages may contain foreign material (black particles).

We are notifying our customers to take the following actions:

1. Immediately discontinue use and quarantine any products with the catalog numbers and lot numbers provided.
2. If you have affected stock please contact Life-Assist Customer Service, 800-824-6016 or customerservice@life-assist.com, to obtain a Return Authorization.
3. Please complete the enclosed Recall Acknowledgment Form and return the completed form with the affected product.

We apologize for any inconvenience this may cause and remain committed to providing high quality products and services.

Sincerely,

Life-Assist, Inc.



Immediate Attention Requested

First Recall Acknowledgment Form for:

Hudson RCI[®] Humidifier Adaptor

Please complete and return this form **ONLY** if you have affected product **Contact Life-Assist Customer Service to obtain a Return Authorization 800-824-6016 | customerservice@life-assist.com**

- We have no inventory within the scope of this recall.
- We have the following affected product at our facility and have discontinued use and distribution. We have quarantined the affected product, and will return the following quantities.

Product Code	Lot Number(s)	Quantity	Product Code	Lot Number(s)	Quantity
OH0340			OH0640		

RGA # (obtain from Customer Service)	
Form Completed by: (Print Name)	Title
Signature	Date
Life-Assist Account#	Telephone Number
Facility Name	Email Address
Facility Street Address	Billing Address (if different)
Facility City, State, Zip	Billing City, State, Zip (if different)



Product Code 003-40; Lot #s:

062137	323137	262137	272147	561137	084147	239147
060137	407147	095137	184147	215147	343147	455137
038137	605137	201137	171137	278137	445137	513137
039137	293147	252137	095147	089137	237147	456137
054137	294137	571137	311147	555137	070147	593137
088137	639137	155147	617137	140137	241147	048147
445147	166137	112137	043137	557137	514137	079147
052137	306147	114137	136137	559137	229147	094147
051137	264147	359137	458137	060147	089147	098137
380137	138147	308147	581137	148137	028147	240147
055137	604137	280137	435137	131147	219147	603137
167137	034147	050147	222147	461137	031147	251137
176137	534137	141137	349147	460137	080147	522137
271147	271137	599137	403147	446137	273147	498137
356147	099137	139147	173137	185147	377137	529137
585137	190137	156147	054147	255147	277137	159147
260147	371137	177137	400147	071147	296147	315147
625137	369137	630137	235137	442147	341147	376147
131137	137147	261147	320137	077137	331147	050137
113147	225147	373147	450137	164137	526137	392147
279137	239137	497137	306137	449137	394147	085147
281137	651137	544137	640137	087137	340147	438137
083137	237137	274147	218147	152137	072137	168137
285147	550137	383147	441137	106147	254137	341137
090147	517137	359147	105137	304147	402147	339147
295147	401147	097147	109137	482137	457137	048137
374137	004147	172147	573137	037147	379147	443137
621137	064137	212147	111137	075137	577137	224137
387147	127137	188137	274137	217147	649137	064147
093137	386147	371147	434137	382147	067137	368147
404147	056137	097137	576137	289147	520137	073137
088147	100137	288147	510137	495137	220147	442137
333147	157137	289137	117137	045137	368137	056147
059147	224147	541137	375137	459137	543137	138137
058137	398147	247137	246147	302147	376137	043147
120137	365147	157147	243147	377147	586137	290147
374147	129137	421137	238147	180147	107147	397147
484137	248147	345137	373137	537137	216147	358137
642137	622137	154137	602137	209147	388147	338147
249147	183147	272137	208147	119137	226137	150137
	265137	284137	232147	110147	108137	503137
	351137	266147	081147	126147	304137	123147
	275147	085137	273137	132137	242147	507137
	258137	342147	276137	162137	134147	204137
	432137	195137	439137	319137	090137	300147
	158147	205137	440137	016147	348147	071137
	283137	253137	648137	628137	384147	291147
	399147	170137	268147	179147		221147
	074147	102137	110137	583137		314147
	405147	135137	270147	308137		312147



Product Code 006-40; Lot #s:

061136	137136	144136	044146
038146	047136	136136	066146
139136	182136	183136	033136
024136	176136	072136	030136
101136	154136	188136	028136
135136	172136	197136	026136
173136	131136	049146	042146
198136	138136	099136	061146
067136	191136	073136	125136
192136	021146	151136	
177136	190136	041136	
059136	098136	071136	
022146	050146	064146	
067146	156136	065146	
119136	185136	064136	
034136	043136	063136	
045146	096136	066136	
152136	189136	060146	
157136	150136	058136	
042136	044136	065136	
053136	155136	186136	
051146	181136	025136	
100136	184136	097136	
145136	043146	124136	
045136	196136	046136	



Urgent Medical Device Recall Notification

Hudson RCI® Humidifier Adaptor

January 14, 2015

To: Distributor of Teleflex Medical Products

Teleflex has issued a voluntary recall for certain lot numbers of the humidifier adaptors included in the product codes listed below (affected lot numbers listed in separate attachment):

Product Description	Product Code	Product Description	Product Code	Product Description	Product Code
HUMIDIFIER ADAPTOR 040	000-40	AQUAPAK 340 SW,340 ML W/040 ADAPTOR ,FREN	003-40F	AQUAPAK 640 SW,650 ML W/040 ADAPTOR ,FREN	006-40F
AQUAPAK 101 SW,190 ML W/040 ADAPTOR ,JAPA	001-40J	AQUAPA K 340 SW,340 ML W/040 ADAPTOR ,JAPA	003-40J	AQUAPAK 640 SW,650 ML W/040 ADAPTOR ,FREN	006-40J
AQUAPAK 340 SW,340 ML W/040 ADAPTOR	003-40	AQUA 540 SW, 540 W/ 040 ADAPTOR	005-40	ADAPTOR ,040 HUM,INTL	400040
AQUAPAK 340 SW,340 ML W/0408 ADAPTOR,BRI	003-408	AQUAPAK 640 SW,650 ML W/040 ADAPTOR	006-40	AQUAPA K 340 SW,340 ML W/040 ADAPTOR ,INTL	400340
AQUAPAK SW/EAU STERILE,340 ML W/ADAPTOR	003-40C	AQUAPAK SW/EAU STERILE,650 ML W/ADAPTOR	006-40C	AQUAPAK 640 SW,650 ML W/040 ADAPTOR, INTL	400640

Teleflex Medical has issued the recall for these products due to possibility that the packages may contain foreign material (black particles). Teleflex Medical is recalling these products in an effort to provide our customers and their patients with the highest quality product possible.

Our records indicate that you have received products that are subject to the recall. We are notifying our distributors to take the following actions:

1. Immediately discontinue distribution and quarantine any products with the product codes and lot numbers listed in the attachment.
2. Using the provided customer letter and Recall Acknowledgement Form templates, communicate this recall to any of your customers who have received product included within the scope of the recall.
3. Have the customers return any affected product to you, together with a completed Recall Acknowledgement Form, for consolidation and return to Teleflex Medical. In the event that an alternative approach is needed, contact Teleflex Medical Customer Service for more information at 1-866-246-6990.
4. To return product, complete the enclosed Recall Acknowledgement Form and either email it to





recalls@teleflex.com or fax it to 1-855-419-8507, Attn: Customer Service. This will allow us to document the amount of product you have on hand for return. A customer service representative will contact you with a Return Goods Authorization (RGA) Number and will provide instructions for the return of product to Teleflex Medical.

5. If you and your customers have no affected stock, please complete the enclosed Recall Acknowledgment Form and either email it to recalls@teleflex.com or fax it to 1-855-419-8507, Attn: Customer Service. This will allow us to document your receipt of this letter.

Teleflex Medical 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 at 1-866-246-6990.

For and on behalf of Teleflex,

Karen Boylan

Karen Boylan
VP, Global RA/QA

