



July 25, 2023

## **URGENT MEDICAL DEVICE RECALL**

To: Purchasing Department/  
Material Management

From: David Mackie  
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The purpose of this letter is to advise you that Advance Medical Designs, Inc. ("AMD") is voluntarily recalling Turkuaz Medical sterile ultrasound gel and convenience kits which contain Turkuaz Medical sterile ultrasound gel as a component, due to a mislabeling issue.

### **Reason for the Voluntary Recall:**

The instructions for use of Turkuaz Medical sterile ultrasound gel and convenience kits that include Turkuaz Medical sterile ultrasound gel as a component, state that the gel can be used internally, but the correct instruction for use is for *use on intact skin only*. Therefore, the gel packets purchased from Turkuaz Medical, with the lot numbers listed below, are considered mislabeled.

### **Turkuaz Medical Sterile Ultrasound Gel Subject to Recall:**

Part Number	Lot Number
<b>ASG-001</b>	SJ17051019
	SJ18101019
	SJ03011020
	SJ13031020
	SJ13111018
	SJ14021019
	SJ12051020
	SJ19011021
	SJ25031021
	SJ05071021

<b>ASG-001</b>	SJ28101021
	SJ23082022
	SJ06041022

**AMD Convenience Kits and Products that include affected lots of Turkuaz Medical sterile ultrasound gel:**

Part Number	Lot Number	Qty. (ea.)
<b>20-PMT03</b>	20485C0157	500
	20584C0175	6000
	20804C0209	1696
	20892C0221	5795
	21103C0256	3675
	10197C1093	1500
	10227C1107	8491
	10481C1143	8975
	10830C1216	5995
	10975C1247	2200
	220211C2165	11771
	220366C2191	9993
	20715C2259	4991
	20838C2283	4913
	21076C2334	8900
	30305C3261	6999
	30479C3299	9999
	30603C3327	5989
Total:		<b>108,382</b>

Part Number	Lot Number	Qty. (ea.)
<b>20-PMT04</b>	20507C0154	2998
	10374C1127	3894
	220348C2188	5000
	21104C2343	2000
	30331C3268	2000
	30394C3279	3989
Total:		<b>19,881</b>

Part Number	Lot Number	Qty. (ea.)
<b>20-PC548</b>	20575C0177	31500
	20809C0210	18000
	21046C0246	10800
	10134C1086	13500

<b>20-PC548</b>	10213C1096	11588
	10274C1109	7793
	10441C1137	27000
	10548C1161	9575
	10719C1194	22193
	10949C1243	15775
	220176C2157	35000
	220383C2195	38787
	20720C2260	26950
	21088C2341	22800
	30324C3267	22500
	30353C3268	13500
	20240C2144	62500
	Total:	<b>304,373</b>

Part Number	Lot Number	Qty. (ea.)
<b>50-GEL20</b>	20708C0198	3942
	21057C0069	11975
	10148C1088	12000
	10373C1126	13400
	10700C1191	12000
	220224C2167	12000
	20512C2221	6392
	20694C2256	7975
	20951C2308	10000
	21043C2328	14400
	30486C3302	12000
	Total:	<b>116,084</b>

Part Number	Lot Number	Qty. (ea.)
<b>20-PC424</b>	20648C0037	975
	20889C0218	975
	10439C1135	984
	10853C1221	175
	10971C1243	775
	220293C2173	975
	20572C2233	991
	21109C2345	992
	30581C3323	1473
	Total:	<b>8,315</b>

Part Number	Lot Number	Qty. (ea.)
<b>20-PC448</b>	20484C0157	9000
	20902C0223	10950
	10510C1154	4500
	10661C1185	2997
	10822C1217	9000
	220294C2174	7490
	20796C2278	13500
	30371C3276	5875
	30622C3333	16200
Total:		<b>79,512</b>

Part Number	Lot Number	Qty. (ea.)
<b>20-PC596</b>	20582C0178	12599
	20963C0230	750
	21012C0241	18000
	10204C1094	6948
	10472C1144	17945
	10952C1243	18000
	220317C2177	17950
	20622C2244	17800
	21103C2343	17975
	30481C3301	19925
Total:		<b>147,892</b>

Part Number	Lot Number	Qty. (ea.)
<b>20-PC648</b>	20017C2017	43950
	20071C0071	44043
	10000C1000	43950
	10048C1030	62500
	10121C1311	62500
	10197C1368	62496
	20145C2088	62538
	20163C2097	62518
Total:		<b>444,495</b>

Part Number	Lot Number	Qty. (ea.)
<b>20-PC696</b>	30633C3336	5400
Total:		<b>5,400</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-EG103</b>	10717C1190	300
Total:		<b>300</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-EG111</b>	10972C1243	20
Total:		<b>20</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-EG125</b>	30552C3318	99
Total:		<b>99</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-EG125LF</b>	220448C2205	70
Total:		<b>70</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-EG135</b>	220221C2163	100
	10634C1175	299
Total:		<b>399</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-EG135LF</b>	220378C2189	50
Total:		<b>50</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-EG147</b>	10690C1188	100
Total:		<b>100</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-EG151</b>	20814C2279	100
	20655C2250	199
Total:		<b>299</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-EG161</b>	10759C1198	60
Total:		<b>60</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-EG163</b>	10614C1166	248
Total:		<b>248</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-EG179</b>	10711C1190	20
Total:		<b>20</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-EG197</b>	20804C2274	100
	10710C1190	100
Total:		<b>200</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG013</b>	10488C1000	50
Total:		<b>50</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG027</b>	10763C1198	20
Total:		<b>20</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG105</b>	21123C2346	247
Total:		<b>247</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG107</b>	30550C3318	239
	21039C2325	400
Total:		<b>639</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG113</b>	220253C2169	100
Total:		<b>100</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG121</b>	21125C2346	390
Total:		<b>390</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG205</b>	220254C2169	100
Total:		<b>100</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG209</b>	10760C1198	20
Total:		<b>20</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG219</b>	30442C2419	70
	30440C2419	100
Total:		<b>170</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG223</b>	21120C2341	99
Total:		<b>99</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG225</b>	220255C2169	100
Total:		<b>100</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG301</b>	10477C1135	250
Total:		<b>250</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG303</b>	10484C1000	246
	30666C3340	80
Total:		<b>326</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG305</b>	10485C1000	250
Total:		<b>250</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG307</b>	30551C3318	159
	20599C2238	350
Total:		<b>509</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG309</b>	10688C1188	250
Total:		<b>250</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG503</b>	10761C1198	20
Total:		<b>20</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG515</b>	10764C1198	20
Total:		<b>20</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG519</b>	20704C2254	240
Total:		<b>240</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG519PC</b>	20709C2256	90
Total:		<b>90</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG521</b>	21126C2346	750
Total:		<b>750</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG521PC</b>	21128C2346	110
Total:		<b>110</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG529</b>	30670C3340	140
Total:		<b>140</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG553</b>	20816C2280	250
	10486C1000	218
Total:		<b>468</b>



Part Number	Lot Number	Qty. (ea.)
<b>28-GG569</b>	21124C2346	300
Total:		<b>300</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG571</b>	30502C2449	697
Total:		<b>697</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG721</b>	10762C1198	20
Total:		<b>20</b>

Part Number	Lot Number	Qty. (ea.)
<b>28-GG723</b>	20705C2256	100
Total:		<b>100</b>

**Actions to be taken by medical facilities:**

- Immediately locate, isolate, and cease all use of all affected products.
- If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.
- Complete the attached Response Form and return it to the contact noted below whether or not you have any of the affected products so that Advance Medical Designs may acknowledge your receipt of this notification per FDA requirements.
- If your facility has any of the above reference lots of products, please contact Advance Medical Designs' Customer Service Manager, Carrie Farmer at [carriefarmer@advmeddes.com](mailto:carriefarmer@advmeddes.com), for an RGA number so that the product can be returned.

**Actions to be taken by distributors:**

- Immediately cease all distribution of the affected products.
- Identify all customers within your distribution network that purchased any affected Product as defined in this notification. Provide a copy of this letter to all customers to advise them of this field action notification on our behalf.
- Complete the attached Response Form and return it to the contact noted below whether or not you have any of the affected products so that Advance Medical Designs may acknowledge your receipt of this notification per FDA requirements.
- If your company has any of the above reference lots of products, please contact Advance Medical Designs' Customer Service Manager, Carrie Farmer at [carriefarmer@advmeddes.com](mailto:carriefarmer@advmeddes.com), for an RGA number so that the product can be returned.

Report any adverse health consequences experienced from the use of these products to Advance Medical Design at [mackied@advmeddes.com](mailto:mackied@advmeddes.com)

Events may also be reported to the FDA's MedWatch Adverse Event Reporting program via:

**Web:** MedWatch website at [www.fda.gov/medwatch](http://www.fda.gov/medwatch)

**Phone:** 1-800-FDA-1088 (1-800-332-1088)

**Mail:** MedWatch, HF-2, FDA, 5600 Fisher's Lane, Rockville, MD 20852-97

If you have any questions or concerns, or if you require further explanation of the issue at hand, please do not hesitate to contact me, David Mackie, at [mackied@advmeddes.com](mailto:mackied@advmeddes.com) or Carrie Farmer at [carriefarmer@advmeddes.com](mailto:carriefarmer@advmeddes.com).

We apologize for any inconvenience this issue may have caused and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Regards,



David Mackie  
QA/RA Manager  
Advance Medical Designs, Inc.  
+1 (800) 221-3679  
[mackied@advmeddes.com](mailto:mackied@advmeddes.com)

# MEDICAL DEVICE RECALL RETURN RESPONSE

## Acknowledgement and Receipt Form

Response is Required

### Customer Information:

**Products:** ASG-001  
50-GEL20  
20-PMTxx  
20-PCxxx  
28-EGxxx  
28-GGxxx

### Lot/Serial numbers: Lot numbers located in the Notification Letter

I have read and understand the recall instructions provided in the July 19, 2023, letter.  
Yes \_ No \_

Any adverse events associated with recalled product? Yes \_ No \_

If yes, please explain:

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Product/Brand Names, UDI (if applicable)	Number/Catalog Number	Lot/Serial Number	Quantity in inventory to be returned

**Return Response Box:**

**Please provide any additional information, if applicable.**

Distributors:

I have identified and notified my customers that were shipped or may have been shipped this product by **(specify date and method of notification)**;

**Questions:**

Contact the Regulatory Department at Advance Medical Designs, Inc. at +1 (770) 422-3125

**David Mackie, QA/RA Manager** [mackied@advmeddes.com](mailto:mackied@advmeddes.com)

Or

**Carrie Farmer, Customer Service Manager** [carriefarmer@advmeddes.com](mailto:carriefarmer@advmeddes.com)

☐ Please have Customer Service contact me.

Signature of Receipt \_\_\_\_\_

Name/Title	
Telephone	
Email address	

PLEASE FAX COMPLETED RESPONSE FORM TO: Tel. # +1 (770) 429-2471, ATTN: DAVID MACKIE or CARRIE FARMER.

OR EMAIL TO:

[mackied@advmeddes.com](mailto:mackied@advmeddes.com)

[carriefarmer@advmeddes.com](mailto:carriefarmer@advmeddes.com)

OR MAIL TO:

Advance Medical Designs, Inc.  
1241 Atlanta Industrial Drive  
Marietta, Georgia 30066 USA  
Attn.: David Mackie or Carrie Farmer