



July 25, 2023

URGENT MEDICAL DEVICE RECALL

To: Purchasing Department/
Material Management

From: David Mackie
QA/RA Manager
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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
ASG-001	SJ17051019
	SJ18101019
	SJ03011020
	SJ13031020
	SJ13111018
	SJ14021019
	SJ12051020
	SJ19011021
	SJ25031021
	SJ05071021

ASG-001	SJ28101021
	SJ23082022
	SJ06041022

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

Part Number	Lot Number	Qty. (ea.)
20-PMT03	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:		108,382

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

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

20-PC548	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:	304,373

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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, 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, 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

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

Web: MedWatch website at 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 or Carrie Farmer at 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,

A handwritten signature in blue ink, appearing to read "D. Mackie", written in a cursive style.

David Mackie
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Advance Medical Designs, Inc.
+1 (800) 221-3679
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:

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

Or

Carrie Farmer, Customer Service Manager 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

carriefarmer@advmeddes.com

OR MAIL TO:

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