

Field Safety Notice – Batch Recall

smartbag - Neodymium contamination

Date: July 31, 2026

Dear Valued Customer,

During an inspection, Fresenius Medical Care identified a defective pump that was used in the manufacturing process. The defective pump has already been replaced but testing of prior produced smartbags revealed sporadic presence of neodymium, a lanthanide metal which leached from the magnetic drive in the pump.

Although a legal limit for neodymium is not provided, the level detected was evaluated in a toxicological risk assessment. Due to the limited toxicological data available for neodymium, a conservative approach was taken to assess potential toxicity from chronic intake in adults and children by using also data from analogue substances of lanthanide metals.

Fresenius Medical Care has not received any reports of adverse health effects related to potentially affected products.

However, when considering a worst-case exposure scenario and applying high safety margins, potential bioaccumulation and toxicological effects cannot be ruled out. Therefore, usage of the affected products should be avoided to minimize any potential risks.

It is important to note that during production, two separate filling machines (lines A and M) process one batch. The defective pump was only located in line M.

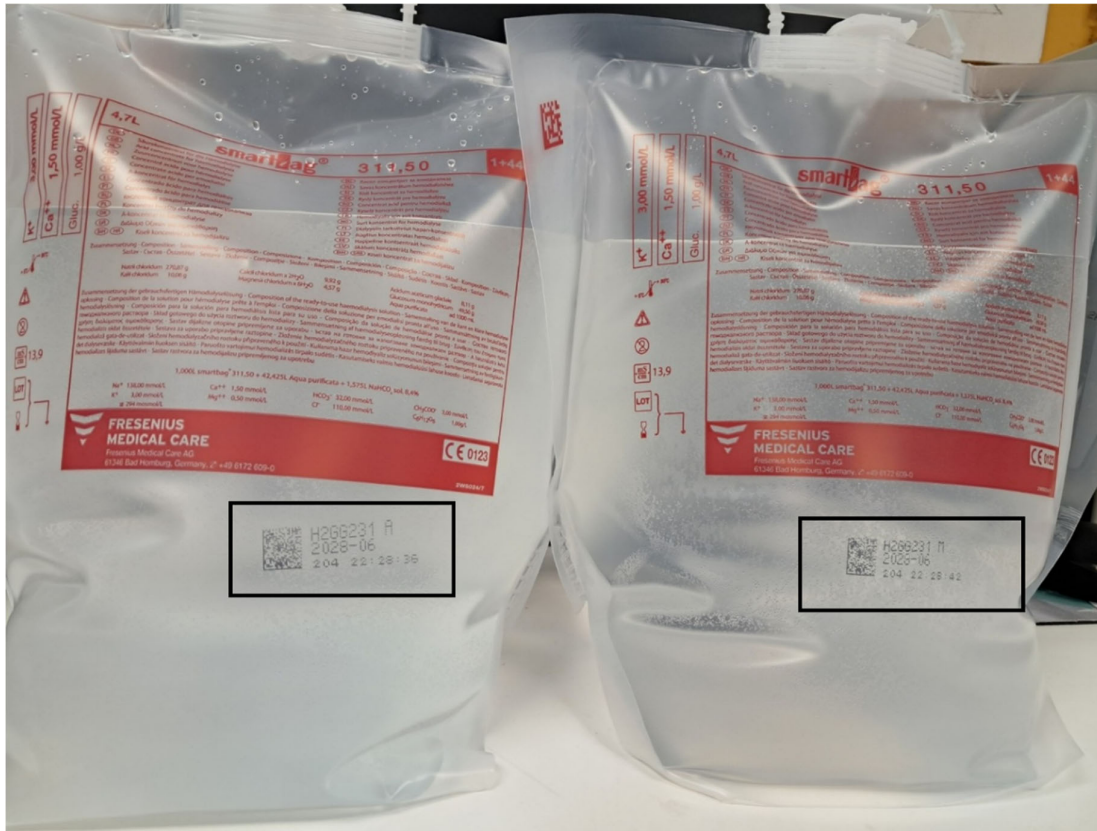
The bags are labelled to indicate whether they were filled in line A or M (see picture 1 for an overview and picture 2 for more details).

Only bags from line M should no longer be used, while bags from line A are not affected!

One box of smartbags can contain bags from both filling lines, A and M. This identification letter is not part of the batch number printed on the box. Thus, it is necessary to:

1. Identify if you have affected batches on stock – refer to Annex I.
2. Open the boxes (i) with the first letters **G2G** or **H2G** on the printed batch and (ii) with an expiry date from **2027-04** to **2028-03** (see picture 2).
3. Inspect the variable data printed on the bags (see picture 1).
4. Identify the affected smartbags with M and separate (see picture 2).
5. Follow the instructions provided by our local contact person for the return or discarding of smartbags with M.

The use of affected smartbags should be discontinued immediately. Please refer to Annex I for potentially affected batches.



Picture 1. smartbags labeling – batch number overview. The bag print shows whether the smartbags were filled on line A or M.



Picture 2. smartbags labeling – details. “A” after the batch number represents smartbags filled from line A that are OK to be used. “M” after the batch number represents smartbags from line M that must not be used!



We sincerely apologize for any inconvenience this may cause. Fresenius Medical Care is committed to ensure that our products and services consistently meet the highest standards of quality and safety for patients and healthcare providers.

Please distribute this recall notice to everyone in your organisation who needs to be aware of it.

In case of any further questions do not hesitate to contact:

medical-device-safety@freseniusmedicalcare.com

Sincerely yours,

Signed by:

60544617225D47B...

Montserrat Galera Conejo

Quality Assurance Manager/ LMR
Manufacturing Quality

Marco Zimmer

Vice President
International MD Vigilance & PMS



Annex I: Only smartbags with “M” after the batch number are potentially affected!

Article Code	Article Name and Expiry Date	Batches							
F0000064D	smartbag 111,5 (4.7Lx2) Expiry date 2027-04, 2027-08	G2GE304	G2GE305	G2GI191	G2GI192				
F0000065D	smartbag 211.25 (4.7Lx2) Expiry date 2027-04, 2027-06, 2027-07, 2027-08, 2027-09, 2027-10, 2027-11, 2027-12, 2028-01, 2028-02	G2GE201	G2GE202	G2GE203	G2GE204	G2GE211	G2GE212	G2GG014	G2GG015
		G2GG021	G2GG022	G2GG023	G2GG024	G2GG031	G2GG033	G2GG034	G2GG035
		G2GG143	G2GG144	G2GG145	G2GH282	G2GH283	G2GH284	G2GH285	G2GH291
		G2GI021	G2GI175	G2GI181	G2GI182	G2GI183	G2GK077	G2GK078	G2GK079
		G2GK081	G2GK083	G2GK163	G2GK164	G2GK165	G2GK233	G2GK234	G2GK235
		G2GK241	G2GL061	G2GL062	G2GL063	G2GL064	G2GL065	G2GL071	G2GL072
		G2GL073	G2GL074	G2GL075	G2GL091	G2GL101	G2GL184	G2GL185	G2GL186
		G2GL191	G2GL192	G2GL193	G2GL301	G2GM011	G2GM012	G2GM013	G2GM014
		G2GM021	G2GM022	G2GM091	G2GM092	G2GM093	G2GM094	G2GM095	G2GM101
		G2GM173	G2GM175	G2GM181	G2GM182	G2GM183	G2GM184	G2GM193	G2GM194
		G2GM195	G2GM221	H2GA161	H2GA162	H2GA163	H2GA164	H2GA221	H2GA222
		H2GA223	H2GA224	H2GA225	H2GA231	H2GA232	H2GA233	H2GA234	H2GA251
		H2GA261	H2GB054	H2GB055	H2GB061	H2GB062	H2GB063	H2GB064	H2GB091
		H2GB133	H2GB134	H2GB135	H2GB151	H2GB161	H2GB162	H2GB163	H2GB164
		H2GB165	H2GB171	H2GB172	H2GB193	H2GB194	H2GB195	H2GB201	H2GB202
		H2GB203	H2GB204	H2GC026	H2GC031	H2GC032	H2GC033	H2GC034	H2GC041
		H2GC042	H2GC043	H2GC121	H2GC122	H2GC123	H2GC124	H2GC125	H2GC131
		H2GC132	H2GC133						
F0000066D	smartbag 211.5 (4.7Lx2) Expiry date 2027-04, 2027-05, 2027-06, 2027-08, 2027-09, 2027-10, 2027-11, 2027-12, 2028-01, 2028-02, 2028-03	G2GE261	G2GE262	G2GE263	G2GE264	G2GE265	G2GE271	G2GE272	G2GF061
		G2GF062	G2GF063	G2GF064	G2GF191	G2GF192	G2GF201	G2GF251	G2GF252
		G2GF253	G2GF254	G2GF255	G2GF261	G2GF262	G2GF263	G2GF264	G2GF271
		G2GG084	G2GG085	G2GG091	G2GG092	G2GG093	G2GG094	G2GG151	G2GG152
		G2GG153	G2GG154	G2GI032	G2GI033	G2GI034	G2GI093	G2GI094	G2GI095
		G2GI101	G2GI102	G2GI103	G2GI161	G2GI162	G2GI242	G2GI243	G2GI244
		G2GI251	G2GI252	G2GK211	G2GK212	G2GK213	G2GK214	G2GK215	G2GL114
		G2GL121	G2GL122	G2GL123	G2GL124	G2GL125	G2GL126	G2GL127	G2GL131
		G2GM032	G2GM033	G2GM034	G2GM041	G2GM042	G2GM043	G2GM044	G2GM045
		H2GA201	H2GA202	H2GA203	H2GA204	H2GB111	H2GB112	H2GB113	H2GB114
		H2GB205	H2GB231	H2GB232	H2GB233	H2GB234	H2GB235	H2GB236	H2GC175
		H2GC181	H2GC182	H2GC183	H2GC231	H2GC232	H2GC233	H2GC234	H2GC235
		H2GC241	H2GC242	H2GC243	H2GC244	H2GD072	H2GD073	H2GD074	H2GD075
		H2GD076	H2GD081						
F0000067D	smartbag 311,25 (4.7Lx2) Expiry date 2027-04, 2027-05, 2027-08, 2027-09, 2027-10, 2028-02	G2GE232	G2GE233	G2GE235	G2GE236	G2GF302	G2GF303	G2GI044	G2GK084
		G2GK085	G2GK091	G2GL171	G2GL172	G2GL173	G2GL174	H2GC184	H2GC185
		H2GC191	H2GC262						



F0000068D	smartbag 311,5 (4.7Lx2) Expiry date 2027-04, 2027-05, 2027-06, 2027-07, 2027-08, 2027-09, 2027-10, 2027-11, 2027-12, 2028-01, 2028-02, 2028-03	G2GE213	G2GE214	G2GE221	G2GE222	G2GE223	G2GE224	G2GE225	G2GE231
		G2GF011	G2GF012	G2GF021	G2GF022	G2GF023	G2GF173	G2GF174	G2GF181
		G2GF182	G2GF183	G2GF184	G2GF185	G2GG164	G2GG165	G2GG171	G2GH265
		G2GH271	G2GH272	G2GH273	G2GH274	G2GH281	G2GI084	G2GI091	G2GI092
		G2GI163	G2GI171	G2GI172	G2GI173	G2GI174	G2GK171	G2GK172	G2GK173
		G2GK174	G2GK191	G2GK201	G2GK202	G2GK203	G2GK204	G2GL132	G2GL133
		G2GL134	G2GL141	G2GL282	G2GL283	G2GL284	G2GM151	G2GM152	G2GM153
		G2GM154	G2GM155	G2GM161	H2GA205	H2GA211	H2GA212	H2GA213	H2GB094
		H2GB095	H2GB096	H2GB101	H2GB102	H2GB103	H2GB104	H2GB174	H2GB181
		H2GB182	H2GB245	H2GB251	H2GB252	H2GB253	H2GB254	H2GB255	H2GC192
		H2GC193	H2GC194	H2GC195	H2GC201	H2GC202	H2GC203	H2GD083	
F0000232D	smartbag 211,75 (4.7Lx2) Expiry date 2027-04, 2027-05, 2027-06, 2027-07, 2027-08, 2027-09, 2027-10, 2027-11, 2027-12, 2028-01, 2028-02	G2GE161	G2GE162	G2GE163	G2GE164	G2GE273	G2GE274	G2GE281	G2GE282
		G2GE283	G2GE284	G2GE285	G2GE286	G2GE291	G2GE292	G2GE293	G2GE294
		G2GE295	G2GE301	G2GE302	G2GE303	G2GF133	G2GF161	G2GF162	G2GF163
		G2GF164	G2GF165	G2GF171	G2GF172	G2GG032	G2GG041	G2GG042	G2GG043
		G2GG172	G2GG173	G2GH251	G2GH252	G2GH253	G2GH254	G2GH255	G2GH261
		G2GH262	G2GH263	G2GH264	G2GI051	G2GI052	G2GI053	G2GI211	G2GI221
		G2GI222	G2GI223	G2GI224	G2GK064	G2GK065	G2GK071	G2GK072	G2GK073
		G2GK074	G2GK075	G2GK076	G2GK103	G2GK131	G2GL181	G2GL182	G2GL271
		G2GL272	G2GL273	G2GL274	G2GL275	G2GM111	G2GM112	G2GM113	G2GM114
		G2GM115	G2GM121	G2GM122	G2GM123	G2GM124	G2GM141	G2GM185	G2GM186
		G2GM191	G2GM192	G2GM232	G2GM233	H2GA071	H2GA072	H2GA073	H2GA074
		H2GA075	H2GA081	H2GA082	H2GA083	H2GA084	H2GA085	H2GA273	H2GA274
		H2GA275	H2GA281	H2GA282	H2GA283	H2GA284	H2GA285	H2GA291	H2GB106
		H2GB261	H2GB262	H2GB263	H2GB264	H2GB265	H2GB271	H2GB272	H2GB273
		H2GB274	H2GB275	H2GC052	H2GC053	H2GC063	H2GC065	H2GC134	H2GC135
		H2GC161	H2GC162	H2GC163	H2GC164	H2GC165	H2GC171	H2GC172	H2GC204
		H2GC221							
F00005286	smartbag CA 211,5 (4.7Lx2) Expiry date 2027-05, 2027-06, 2027-08, 2027-09, 2027-10, 2027-12, 2028-01, 2028-02	G2GF105	G2GF112	G2GG212	G2GG213	G2GG214	G2GG215	G2GG221	G2GG222
		G2GG223	G2GG224	G2GG231	G2GG232	G2GG233	G2GG234	G2GG235	G2GI291
		G2GI292	G2GI293	G2GI294	G2GI295	G2GI301	G2GI302	G2GK294	G2GK295
		G2GK301	G2GK302	G2GK303	G2GK304	G2GK311	G2GL201	G2GL202	G2GL203
		G2GL204	G2GL205	G2GL211	G2GL212	H2GA091	H2GA092	H2GA093	H2GA094
		H2GA121	H2GA122	H2GA123	H2GA124	H2GA125	H2GA131	H2GA132	H2GA133
		H2GA134	H2GB021	H2GB022	H2GB023	H2GB024	H2GB025	H2GC114	H2GC115
F00005287	smartbag CA 311,5 (4.7Lx2) Expiry date 2027-05, 2027-06, 2027-08, 2027-09, 2027-10, 2027-12, 2028-01, 2028-02	G2GF114	G2GF122	G2GG253	G2GG254	G2GG271	G2GG281	G2GG282	G2GG283
		G2GG284	G2GG291	G2GG292	G2GG293	G2GG294	G2GG297	G2GI303	G2GI304
		G2GK011	G2GK012	G2GK013	G2GK014	G2GK015	G2GK016	G2GK021	G2GL033
		G2GL034	G2GL041	G2GL042	G2GL043	G2GL213	G2GL214	G2GL231	G2GL241
		H2GA142	H2GA143	H2GA144	H2GA151	H2GA152	H2GB031	H2GB032	H2GB033
		H2GB034	H2GC095	H2GC101	H2GC102	H2GC103			



F00005537	smartbag CA 211,75 (4.7Lx2) Expiry date 2027-05, 2027-06, 2027-07, 2027-08, 2027-09, 2027-10, 2027-12, 2028-02	G2GF091	G2GF092	G2GF093	G2GF094	G2GF101	G2GF103	G2GG298	G2GG301
		G2GG302	G2GG303	G2GG304	G2GG305	G2GG311	G2GG312	G2GG313	G2GG314
		G2GH011	G2GH012	G2GH013	G2GI253	G2GI254	G2GI255	G2GI261	G2GI262
		G2GI263	G2GK033	G2GK051	G2GK061	G2GK062	G2GK063	G2GK242	G2GK243
		G2GK244	G2GK245	G2GK246	G2GK247	G2GK248	G2GK261	G2GK271	G2GK272
		G2GK273	G2GL044	G2GL045	G2GL051	G2GL052	G2GL053	G2GL243	G2GL244
		G2GL251	G2GL252	G2GL253	G2GL254	G2GL255	G2GL261	G2GL262	G2GL263
		G2GL264	H2GA153	H2GA154	H2GA155	H2GA292	H2GA293	H2GA294	H2GA295
		H2GA301	H2GA302	H2GA303	H2GA304	H2GC105	H2GC106	H2GC111	H2GC112
		H2GC113							
F00005538	smartbag CA 311,75 (4.7Lx2) Expiry date 2027-06, 2027-09, 2027-10, 2028-01, 2028-02	G2GG237	G2GG241	G2GG242	G2GG243	G2GG244	G2GG245	G2GG251	G2GG252
		G2GK024	G2GK025	G2GK026	G2GK031	G2GK032	G2GK274	G2GK275	G2GK281
		G2GK282	G2GK283	G2GK284	G2GK285	G2GK291	G2GK292	G2GK293	G2GL242
		H2GB044	H2GC081	H2GC091	H2GC092	H2GC093	H2GC094		
F00006557	smartbag CA 211.5 (4.2Lx2) Expiry date 2027-06, 2027-09, 2027-12	G2GG182	G2GG183	G2GG184	G2GG211	G2GK312	H2GA135		
F00006560	smartbag CA 411.5 (4.2Lx2) Expiry date 2027-05, 2027-10, 2028-01	G2GF131	G2GL021	H2GB043					
F00006883	smartbag 111.25 (4.7L x2) Expiry date 2027-11	G2GM107							
F00007041	smartbag 411,25 (4.7L x2) Expiry date 2027-04, 2027-05, 2027-06, 2027-09, 2028-02	G2GE234	G2GF304	G2GG011	G2GK232	H2GC021	H2GC022		
F00007043	smartbag CA 211,50-0.75 (4.2L x2) Expiry date 2027-08, 2027-12, 2028-01	G2GI264	H2GA141	H2GB173					
F00007046	smartbag CA 311,50-0.75 (4.2L x2) Expiry date 2027-06, 2027-09	G2GG236	G2GK023	G2GK313	G2GK314	H2GB042			
F00007575	smartbag 311.75 (4.7L x2) Expiry date 2027-05	G2GF024							
F00007576	smartbag 411.50 (4.7L x2) Expiry date 2027-11, 2028-01	G2GM106	H2GB105						
F00007957	smartbag 111.25 (4.2L x2) Expiry date 2027-09	G2GK094							



F00007958	smartbag 111.50 (4.2L x2) Expiry date 2027-06, 2028-03	G2GG105	G2GG111	H2GD082					
F00007959	smartbag 211.25 (4.2L x2) Expiry date 2027-05, 2027-06, 2027-07, 2027-08, 2027-09, 2027-10, 2027-11, 2027-12, 2028-01, 2028-02	G2GF031	G2GF032	G2GF033	G2GF034	G2GF035	G2GF041	G2GF042	G2GF043
		G2GF044	G2GF051	G2GG112	G2GG113	G2GG114	G2GG115	G2GG116	G2GG141
		G2GG142	G2GH293	G2GH294	G2GH295	G2GI011	G2GI012	G2GI013	G2GI081
		G2GI082	G2GI083	G2GI184	G2GI185	G2GI186	G2GK144	G2GK151	G2GK152
		G2GK153	G2GK154	G2GK161	G2GK162	G2GL102	G2GL103	G2GL104	G2GL111
		G2GM102	G2GM103	G2GM104	G2GM105	G2GM164	G2GM165	G2GM171	G2GM172
		G2GM222	G2GM223	G2GM224	H2GA191	H2GA192	H2GA193	H2GA262	H2GA263
		H2GA264	H2GB045	H2GB051	H2GB052	H2GB053	H2GB092	H2GB093	H2GB183
		H2GB184	H2GB185	H2GB191	H2GB192	H2GC263	H2GC264	H2GC265	H2GC271
		H2GC272	H2GC273						
F00007960	smartbag 211.50 (4.2L x2) Expiry date 2027-04, 2027-05, 2027-06, 2027-08, 2027-09, 2027-10, 2027-11, 2027-12, 2028-01, 2028-02, 2028-03	G2GE191	G2GE192	G2GE193	G2GE194	G2GE195	G2GF052	G2GF053	G2GF054
		G2GF055	G2GG012	G2GG013	G2GG071	G2GG072	G2GG073	G2GG081	G2GG082
		G2GG083	G2GG161	G2GG162	G2GG163	G2GI014	G2GI015	G2GI022	G2GI023
		G2GI024	G2GI025	G2GI031	G2GI232	G2GI233	G2GI234	G2GK132	G2GK133
		G2GK134	G2GK135	G2GK141	G2GK142	G2GK143	G2GK221	G2GK222	G2GK223
		G2GK224	G2GL112	G2GL113	G2GM023	G2GM024	G2GM025	G2GM031	G2GM162
		G2GM163	G2GM225	G2GM231	H2GA194	H2GA195	H2GB115	H2GB121	H2GB122
		H2GB123	H2GB124	H2GB125	H2GB241	H2GB242	H2GB243	H2GB244	H2GC044
		H2GC045	H2GC051	H2GC173	H2GC174	H2GC245	H2GC251	H2GC252	H2GC253
		H2GC254	H2GC274	H2GD071					
F00007961	smartbag 211.75 (4.2L x2) Expiry date 2027-06, 2027-09, 2027-10, 2027-12, 2028-01	G2GG044	G2GG061	G2GG174	G2GG181	G2GK101	G2GK102	G2GL183	G2GL281
		H2GA271	H2GA272	H2GB107					
F00007962	smartbag 311,25 (4.2L x2) Expiry date 2027-05, 2027-06, 2027-08, 2027-09, 2027-10, 2027-11, 2027-12, 2028-01, 2028-02	G2GF272	G2GF273	G2GF291	G2GF301	G2GG101	G2GG102	G2GG103	G2GG104
		G2GI041	G2GI042	G2GI043	G2GI225	G2GI231	G2GK092	G2GK093	G2GK225
		G2GK231	G2GL142	G2GL143	G2GL144	G2GL161	G2GM051	G2GM052	G2GM053
		H2GA214	H2GB131	H2GB132	H2GC023	H2GC024	H2GC025	H2GC255	H2GC261
F0002007D	smartbag CA 311,5 (4.2Lx2) Expiry date 2027-05, 2027-09, 2027-10, 2028-01	G2GF124	G2GK022	G2GL031	G2GL032	H2GB035	H2GB041		