

Field Safety Notice

Leakage of 4008 S V10 disinfection solenoid valves

Date: April 03rd, 2025

Dear Valued Customer,

Fresenius Medical Care discovered during quality controls a production issue leading to a potentially leaking disinfection valve (V84) in the 4008 S V10 hemodialysis machine. A kinked hose on our manual disinfection valve workstation was causing a leak test for the valve to give "false positive" test results. As a result, potentially leaking valves were not correctly identified and replaced in production. These were processed further and ended up in production for certain 4008 S V10 devices (see Appendix 1 for the serial numbers) and as spare parts.

The faulty valves could lead to hazardous situations due to insufficient disinfection. While it can be excluded that disinfectant agent are infused into the patient, as the disinfection valve is positioned downstream of the dialyzer, the backflow of fluid from the device through a leaky valve leads to dilution of disinfectant in the container. This could lead to a hazardous situation to the patient due to insufficient disinfection of the device.

Fresenius Medical Care has not received any complaints or incidents on this topic.

Potentially faulty solenoid valves can be identified by a technician, as they do not have a serial number printed on the label and were produced from calendar week 49/2024 to calendar week 05/2025 (Tab.1).

Table 1: Affected Products

Product Name	Product Code
4008 S V10	M204001
Spare part: Solenoid valve V84	M388601 (produced in CW49/2024 – CW05/2025)

Potentially faulty solenoid valves can be identified:

Affected solenoid valves from calendar week 49/24 to calendar week 05/25 (Fig. 1).



Fig.1: **No serial number** on the bottom left label

Solenoid valves **not affected** (Fig. 2).



Fig.2: **Serial number** on label present

Potentially affected devices and those that received the above-mentioned spare parts need to be checked and affected solenoid valves need to be replaced.

Until a Fresenius Medical Care technician has performed the checks, Fresenius Medical Care recommends that healthcare providers do the following:

The affected 4008 S V10 devices (see Appendix 1) and those that received the above-mentioned spare parts must not be used for treatments until the solenoid valve V84 has been replaced. Please also discard and replace the disinfectant canister used for those affected devices.

Please apply adequate treatment by other means. Consult the responsible physician.

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 Safety Notice to all those within your organization who need to be aware of it.

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

Name (*Please adapt locally*)

Telephone (*Please adapt locally*)

E-mail XXX@freseniusmedicalcare.com (*Please adapt locally*)

Sincerely yours,

Name and Signature (*please adapt locally*)

Appendix 1:

No	Name	ArticleNo.	Serial No.	No	Name	ArticleNo.	Serial No.	No	Name	ArticleNo.	Serial No.
1	4008 S V10	M204001	5SXA5SG2	74	4008 S V10	M204001	5SXA5SJY	147	4008 S V10	M204001	5SXA5U7Z
2	4008 S V10	M204001	5SXA5SG3	75	4008 S V10	M204001	5SXA5SJZ	148	4008 S V10	M204001	5SXA5U80
3	4008 S V10	M204001	5SXA5SG4	76	4008 S V10	M204001	5SXA5SKA	149	4008 S V10	M204001	5SXA5U81
4	4008 S V10	M204001	5SXA5SG5	77	4008 S V10	M204001	5SXA5SKB	150	4008 S V10	M204001	5SXA5U82
5	4008 S V10	M204001	5SXA5SG6	78	4008 S V10	M204001	5SXA5SKC	151	4008 S V10	M204001	5SXA5U83
6	4008 S V10	M204001	5SXA5SG7	79	4008 S V10	M204001	5SXA5SKD	152	4008 S V10	M204001	5SXA5U84
7	4008 S V10	M204001	5SXA5SJE	80	4008 S V10	M204001	5SXA5SK0	153	4008 S V10	M204001	5SXA5U85
8	4008 S V10	M204001	5SXA5SJF	81	4008 S V10	M204001	5SXA5SK1	154	4008 S V10	M204001	5SXA5U9J
9	4008 S V10	M204001	5SXA5SJG	82	4008 S V10	M204001	5SXA5SK2	155	4008 S V10	M204001	5SXA5U9K
10	4008 S V10	M204001	5SXA5SJH	83	4008 S V10	M204001	5SXA5SK3	156	4008 S V10	M204001	5SXA5U9L
11	4008 S V10	M204001	5SXA5SJJ	84	4008 S V10	M204001	5SXA5SK4	157	4008 S V10	M204001	5SXA5U9M
12	4008 S V10	M204001	5SXA5SJK	85	4008 S V10	M204001	5SXA5SK5	158	4008 S V10	M204001	5SXA5U9N
13	4008 S V10	M204001	5SXA5S JL	86	4008 S V10	M204001	5SXA5SK6	159	4008 S V10	M204001	5SXA5U9P
14	4008 S V10	M204001	5SXA5SJM	87	4008 S V10	M204001	5SXA5SK7	160	4008 S V10	M204001	5SXA5U9Q
15	4008 S V10	M204001	5SXA5SJN	88	4008 S V10	M204001	5SXA5SK8	161	4008 S V10	M204001	5SXA5U9R
16	4008 S V10	M204001	5SXA5SJP	89	4008 S V10	M204001	5SXA5SK9	162	4008 S V10	M204001	5SXA5NFC
17	4008 S V10	M204001	5SXA5SJQ	90	4008 S V10	M204001	5SXA5SNL	163	4008 S V10	M204001	5SXA5NFD
18	4008 S V10	M204001	5SXA5SJR	91	4008 S V10	M204001	5SXA5SNM	164	4008 S V10	M204001	5SXA5NFE
19	4008 S V10	M204001	5SXA5SJS	92	4008 S V10	M204001	5SXA5SNN	165	4008 S V10	M204001	5SXA5NFF
20	4008 S V10	M204001	5SXA5SJT	93	4008 S V10	M204001	5SXA5SNP	166	4008 S V10	M204001	5SXA5NFG
21	4008 S V10	M204001	5SXA5SJU	94	4008 S V10	M204001	5SXA5SNQ	167	4008 S V10	M204001	5SXA5NFH
22	4008 S V10	M204001	5SXA5SNA	95	4008 S V10	M204001	5SXA5SNR	168	4008 S V10	M204001	5SXA5NFV
23	4008 S V10	M204001	5SXA5SNB	96	4008 S V10	M204001	5SXA5SNS	169	4008 S V10	M204001	5SXA5NFW
24	4008 S V10	M204001	5SXA5SNC	97	4008 S V10	M204001	5SXA5SNT	170	4008 S V10	M204001	5SXA5NFY
25	4008 S V10	M204001	5SXA5SND	98	4008 S V10	M204001	5SXA5SNU	171	4008 S V10	M204001	5SXA5NG0
26	4008 S V10	M204001	5SXA5SNE	99	4008 S V10	M204001	5SXA5SNV	172	4008 S V10	M204001	5SXA5SGH
27	4008 S V10	M204001	5SXA5SNF	100	4008 S V10	M204001	5SXA5SNW	173	4008 S V10	M204001	5SXA5SGJ
28	4008 S V10	M204001	5SXA5SNG	101	4008 S V10	M204001	5SXA5SNX	174	4008 S V10	M204001	5SXA5SGK
29	4008 S V10	M204001	5SXA5SNH	102	4008 S V10	M204001	5SXA5SNY	175	4008 S V10	M204001	5SXA5SGN
30	4008 S V10	M204001	5SXA5SNJ	103	4008 S V10	M204001	5SXA5SNZ	176	4008 S V10	M204001	5SXA5SL0
31	4008 S V10	M204001	5SXA5SNK	104	4008 S V10	M204001	5SXA5SP0	177	4008 S V10	M204001	5SXA5SL1
32	4008 S V10	M204001	5SXA5SN2	105	4008 S V10	M204001	5SXA5SP1	178	4008 S V10	M204001	5SXA5STN
33	4008 S V10	M204001	5SXA5SN3	106	4008 S V10	M204001	5SXA5SP2	179	4008 S V10	M204001	5SXA5STP
34	4008 S V10	M204001	5SXA5SN4	107	4008 S V10	M204001	5SXA5SP3	180	4008 S V10	M204001	5SXA5STQ
35	4008 S V10	M204001	5SXA5SN5	108	4008 S V10	M204001	5SXA5SP4	181	4008 S V10	M204001	5SXA5STR
36	4008 S V10	M204001	5SXA5SN6	109	4008 S V10	M204001	5SXA5SP5	182	4008 S V10	M204001	5SXA5STS
37	4008 S V10	M204001	5SXA5SN7	110	4008 S V10	M204001	5SXA5SP6	183	4008 S V10	M204001	5SXA5SVA
38	4008 S V10	M204001	5SXA5SN8	111	4008 S V10	M204001	5SXA5SP7	184	4008 S V10	M204001	5SXA5SVB
39	4008 S V10	M204001	5SXA5SN9	112	4008 S V10	M204001	5SXA5SSA	185	4008 S V10	M204001	5SXA5SVC
40	4008 S V10	M204001	5SXA5SQA	113	4008 S V10	M204001	5SXA5SSB	186	4008 S V10	M204001	5SXA5SV8
41	4008 S V10	M204001	5SXA5SS4	114	4008 S V10	M204001	5SXA5SSC	187	4008 S V10	M204001	5SXA5SWT
42	4008 S V10	M204001	5SXA5SS5	115	4008 S V10	M204001	5SXA5SSD	188	4008 S V10	M204001	5SXA5SWU
43	4008 S V10	M204001	5SXA5SS6	116	4008 S V10	M204001	5SXA5SSE	189	4008 S V10	M204001	5SXA5SWW
44	4008 S V10	M204001	5SXA5SS7	117	4008 S V10	M204001	5SXA5SSF	190	4008 S V10	M204001	5SXA5SWX
45	4008 S V10	M204001	5SXA5STA	118	4008 S V10	M204001	5SXA5SSG	191	4008 S V10	M204001	5SXA5SXL
46	4008 S V10	M204001	5SXA5STB	119	4008 S V10	M204001	5SXA5SS8	192	4008 S V10	M204001	5SXA5SXQ
47	4008 S V10	M204001	5SXA5ST7	120	4008 S V10	M204001	5SXA5SS9	193	4008 S V10	M204001	5SXA5SXS

No	Name	ArticleNo.	Serial No.	No	Name	ArticleNo.	Serial No.	No	Name	ArticleNo.	Serial No.
48	4008 S V10	M204001	5SXA5ST8	121	4008 S V10	M204001	5SXA5STC	194	4008 S V10	M204001	5SXA5SXU
49	4008 S V10	M204001	5SXA5ST9	122	4008 S V10	M204001	5SXA5STD	195	4008 S V10	M204001	5SXA5SXV
50	4008 S V10	M204001	5SXA5SUP	123	4008 S V10	M204001	5SXA5STE	196	4008 S V10	M204001	5SXA5SXW
51	4008 S V10	M204001	5SXA5SUR	124	4008 S V10	M204001	5SXA5STF	197	4008 S V10	M204001	5SXA5SXZ
52	4008 S V10	M204001	5SXA5SUS	125	4008 S V10	M204001	5SXA5STG	198	4008 S V10	M204001	5SXA5SX0
53	4008 S V10	M204001	5SXA5SUT	126	4008 S V10	M204001	5SXA5STH	199	4008 S V10	M204001	5SXA5SX2
54	4008 S V10	M204001	5SXA5SUU	127	4008 S V10	M204001	5SXA5STJ	200	4008 S V10	M204001	5SXA5SX3
55	4008 S V10	M204001	5SXA5SUV	128	4008 S V10	M204001	5SXA5STK	201	4008 S V10	M204001	5SXA5SX4
56	4008 S V10	M204001	5SXA5SUW	129	4008 S V10	M204001	5SXA5STL	202	4008 S V10	M204001	5SXA5SX5
57	4008 S V10	M204001	5SXA5U7N	130	4008 S V10	M204001	5SXA5STM	203	4008 S V10	M204001	5SXA5U9S
58	4008 S V10	M204001	5SXA5U7P	131	4008 S V10	M204001	5SXA5SUX	204	4008 S V10	M204001	5SXA5U9V
59	4008 S V10	M204001	5SXA5U7Q	132	4008 S V10	M204001	5SXA5SUY	205	4008 S V10	M204001	5SXA5NGN
60	4008 S V10	M204001	5SXA5U7R	133	4008 S V10	M204001	5SXA5SUZ	206	4008 S V10	M204001	5SXA5NG1
61	4008 S V10	M204001	5SXA5U7S	134	4008 S V10	M204001	5SXA5SV0	207	4008 S V10	M204001	5SXA5SVK
62	4008 S V10	M204001	5SXA5U7T	135	4008 S V10	M204001	5SXA5SV1	208	4008 S V10	M204001	5SXA5SVS
63	4008 S V10	M204001	5SXA5SGA	136	4008 S V10	M204001	5SXA5SV2	209	4008 S V10	M204001	5SXA5SYB
64	4008 S V10	M204001	5SXA5SGB	137	4008 S V10	M204001	5SXA5SV3	210	4008 S V10	M204001	5SXA5SYY
65	4008 S V10	M204001	5SXA5SGC	138	4008 S V10	M204001	5SXA5SV4	211	4008 S V10	M204001	5SXA5SY1
66	4008 S V10	M204001	5SXA5SGD	139	4008 S V10	M204001	5SXA5SV5	212	4008 S V10	M204001	5SXA5SY2
67	4008 S V10	M204001	5SXA5SGE	140	4008 S V10	M204001	5SXA5SV6	213	4008 S V10	M204001	5SXA5SY5
68	4008 S V10	M204001	5SXA5SGG	141	4008 S V10	M204001	5SXA5SV7	214	4008 S V10	M204001	5SXA5SZ2
69	4008 S V10	M204001	5SXA5SG8	142	4008 S V10	M204001	5SXA5U7U	215	4008 S V10	M204001	5SXA5SZ4
70	4008 S V10	M204001	5SXA5SG9	143	4008 S V10	M204001	5SXA5U7V	216	4008 S V10	M204001	5SXA5UAH
71	4008 S V10	M204001	5SXA5SJV	144	4008 S V10	M204001	5SXA5U7W	217	4008 S V10	M204001	5SXA5UA7
72	4008 S V10	M204001	5SXA5SJW	145	4008 S V10	M204001	5SXA5U7X	218	4008 S V10	M204001	5SXA5UA9
73	4008 S V10	M204001	5SXA5SJX	146	4008 S V10	M204001	5SXA5U7Y	219	4008 S V10	M204001	5SXA5SW2