



## Medical Device Voluntarily Recall Terumo Needle (Neolus)

22<sup>nd</sup> February 2019

Dear Customers,

Cc: Chairman Medical Board and relevant Head of Departments

### Field Safety Notification (FSN) for Terumo Needle (Neolus)

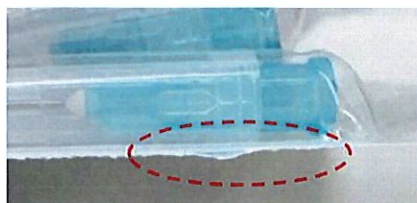
The purpose of this letter is to advise you that Terumo is voluntarily recalling selected lots of Terumo Needle Neolus, with intended use as:

Terumo Needle (Neolus) is used for injection, blood collection, blood transfusion and fluid collection, and which can use immediately as is for one-time use of disposable.

Affected Terumo Needle (Neolus) blister package was observed to have seals narrower or misalignment. Therefore, reason for this voluntarily recall is due the potential loss of package integrity that may compromise the sterility of the product.

Affected Codes	Lot. No.
NN+2025R	180831C
NN+2125R	180910C
NN+2125R	181011C
NN+2325R	180707C
NN+2325R	180917C
NN+2425R	180719C
NN+2425R	180910C
NN+2425R	181030C
NN+2516R	180905C
NN+2516R	180919C
NN+2525R	180704C
NN+2525R	181018C
NN+2613R	180703C
NN+2713R	181024C

The issue originated from a customer complaint that Terumo received claiming that the blister seals are narrow or misaligned. Based on investigation, it was observed that the sealing portion (width) of the blister package was below the manufacturing standard of 1.5mm and a small opening on the package resulting in seal breach was observed.





There have been no reported patient injuries associated to this issue.

No complaint reports have been received regarding infections that may have been associated with the affected products.

The occurrence rate is extremely low, 0.01% for any possibility of a health hazard related to this problem.

Although Terumo realizes this is a challenging situation, and these actions will have a negative impact on our business in the short term, this course of action is necessary because it is the right thing to do for our patients and customers.

At Terumo, patient safety and product quality are at the heart of every decision we make. We ask for your support as we conduct this recall in a manner that is consistent with our company values and principles. Over the longer term, these actions will help to ensure that our manufacturing processes can produce high quality medical devices that our customers require.

Customer Advisory:

Customers are advised to do the following:

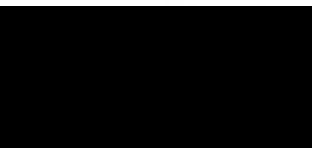
- Promptly identify and confirm if affected product item and lot numbers are in possession.
- Quarantine, discontinue usage/sales of the affected product and return affected devices to Terumo.

Additional Information

Kindly note that device details indicated above are affected identifiers and/or lots received by Terumo Singapore only. For full list of other identifiers and/or lots affected globally, kindly refer to Attachment 1 - Summary of NNP items produced at C-line.

If you have any further questions or comments, please do not hesitate to contact us at 6291 3606 (Office Tel. No.)

Yours Sincerely,



Joyce Soh  
Regulatory Affairs Department

Attachment 1 - Summary of NNP items produced at C-line

SUMMARY OF NNP ITEMS PRODUCED AT C-LINE from June 29, 2018 to Dec. 2018

Items	Item Code	Lot no.	Produced Qty	Shipped Qty.	TPC Inventory
75	NN-2325R	180823C	492,000	492,000	-
76	NN2125R	180824C	720,000	720,000	-
77	NN2125R	180825C	770,000	770,000	-
78	NN2125R	180827C	440,000	440,000	-
79	NN-2613S	180827C	381,000	381,000	-
80	NN-2719S	180828C	720,000	720,000	-
81	NN+2516R	180829C	309,000	309,000	-
82	100279	180829C	400,000	400,000	-
83	100215	180830C	230,000	230,000	-
84	NN+2116R	180830C	123,000	123,000	-
85	NN+2025R	180831C	138,000	138,000	-
86	NN2025R	180831C	150,000	150,000	-
87	NN2025R	180901C	270,000	270,000	-
88	NN2125R	180901C	210,000	210,000	-
89	NN2525R	180901C	30,000	30,000	-
90	NN2225R	180903C	580,000	580,000	-
91	NN2613R	180903C	80,000	79,000	-
92	NN2125R	180904C	720,000	720,000	-
93	NN2125R	180905C	720,000	720,000	-
94	NN+2516R	180905C	471,000	471,000	-
95	NN2516R	180906C	320,000	320,000	-
96	NN3013R	180907C	170,000	170,000	-
97	NN+2713R	180907C	138,000	138,000	-
98	NN2516R	180907C	310,000	310,000	-
99	NN+2425R	180910C	126,000	126,000	-
100	NN+2125R	180910C	159,000	159,000	-
101	NN+2613R	180911C	429,000	429,000	-
102	NN2125R	180912C	500,000	500,000	-
103	NN2125R	180913C	360,000	360,000	-
104	NN+2225R	180914C	144,000	144,000	-
105	NN-2725R	180914C	108,000	108,000	-
106	100204	180915C	260,000	260,000	-
107	NN+2325R	180917C	156,000	156,000	-
108	NN2713R	180918C	90,000	90,000	-
109	NN-2325R	180918C	213,000	213,000	-
110	NN+2516R	180919C	180,000	180,000	-
111	NN-2325R	180921C	816,000	816,000	-
112	NN+2025M	180921C	99,000	99,000	-
113	NN-2325R	180924C	720,000	720,000	-
114	NN-2719S	180925C	681,000	681,000	-
115	NN-2719S	180928C	474,000	474,000	-
116	NN+2325R	180929C	207,000	207,000	-
117	NN2125R	180929C	270,000	270,000	-
118	NN2325R	180929C	240,000	240,000	-
119	NN+2516R	180929C	342,000	342,000	-
120	NN+2519R	181001C	141,000	141,000	-
121	NN2225R	181001C	100,000	100,000	-
122	100280	181002C	340,000	340,000	-
123	NN-2225R	181002C	459,000	459,000	-
124	NN-2425R	181003C	378,000	378,000	-
125	NN3013R	181005C	280,000	280,000	-
126	NN+2225R	181005C	57,000	57,000	-
127	NN-2516R	181005C	399,000	399,000	-
128	NN-2725R	181005C	108,000	108,000	-
129	NN-2525R	181005C	540,000	540,000	-
130	100215	181006C	360,000	360,000	-
131	NN-2719S	181008C	720,000	717,000	-
132	NN-2116R	181009C	792,000	792,000	-
133	NN+2219R	181009C	9,000	9,000	-
134	100280	181009C	220,000	220,000	-
135	NN+2125R	181011C	504,000	33,000	447,000
136	NN-2325R	181011C	831,000	831,000	-
137	NN+2713M	181011C	99,000	99,000	-
138	NN1825R	181011C	260,000	260,000	-
139	NN2713R	181011C	130,000	130,000	-
140	NN2325R	181013C	240,000	240,000	-
141	NN+2325M	181013C	99,000	99,000	-
142	NN-2613S	181015C	405,000	405,000	-
143	100211	181015C	230,000	230,000	-
144	NN-2325R	181016C	369,000	369,000	-
145	NN-2525R	181016C	681,000	681,000	-
146	NN+2525R	181018C	216,000	141,000	69,000
147	NN+2613R	181018C	687,000	687,000	-

SUMMARY OF NNP ITEMS PRODUCED AT C-LINE from June 29, 2018 to Dec. 2018

Items	Item Code	Lot no.	Produced Qty	Shipped Qty.	TPC Inventory
1	NN-2325R	180629C	420,000	420,000	-
2	NN2125R	180702C	450,000	450,000	-
3	NN-2325R	180702C	351,000	351,000	-
4	NN-2525R	180702C	351,000	351,000	-
5	NN2525R	180703C	120,000	120,000	-
6	NN+2516R	180703C	570,000	570,000	-
7	NN+2613R	180703C	117,000	117,000	-
8	NN+2125R	180703C	234,000	231,000	-
9	NN+2525R	180704C	348,000	348,000	-
10	100279	180705C	330,000	330,000	-
11	100220	180706C	510,000	510,000	-
12	NN+2713R	180706C	42,000	42,000	-
13	NN+2325R	180707C	576,000	576,000	-
14	NN2516R	180709C	830,000	830,000	-
15	100204	180709C	500,000	500,000	-
16	NN+2713R	180709C	474,000	471,000	-
17	100211	180710C	160,000	160,000	-
18	NN2025R	180711C	230,000	230,000	-
19	NN+2025R	180711C	60,000	60,000	-
20	NN+2325M	180712C	231,000	231,000	-
21	NN2125R	180712C	470,000	470,000	-
22	NN2025V	180712C	60,000	60,000	-
23	NN-2525R	180713C	306,000	306,000	-
24	NN-2719S	180713C	360,000	360,000	-
25	NN-2116R	180713C	315,000	315,000	-
26	NN1825R	180714C	610,000	610,000	-
27	NN-2516R	180716C	882,000	882,000	-
28	100211	180717C	230,000	230,000	-
29	NN+2425R	180719C	132,000	132,000	-
30	NN-2425R	180719C	117,000	117,000	-
31	100215	180720C	330,000	330,000	-
32	NN+2613R	180720C	759,000	759,000	-
33	NN-2516R	180720C	252,000	252,000	-
34	NN-2325R	180721C	537,000	537,000	-
35	NN+2516M	180721C	306,000	306,000	-
36	NN1825R	180723C	580,000	580,000	-
37	NN2225R	180723C	340,000	340,000	-
38	NN-2613S	180724C	720,000	720,000	-
39	NN-2613S	180728C	402,000	402,000	-
40	NN-2325R	180730C	720,000	720,000	-
41	NN-2325R	180731C	450,000	450,000	-
42	NN-2525R	180731C	273,000	273,000	-
43	NN2125R	180801C	200,000	200,000	-
44	NN-2525R	180801C	267,000	267,000	-
45	NN-2613S	180801C	237,000	237,000	-
46	NN-2516R	180801C	249,000	249,000	-
47	NN+2613R	180802C	252,000	252,000	-
48	NN-2516R	180803C	720,000	720,000	-
49	NN2125R	180803C	660,000	660,000	-
50	NN2613R	180804C	40,000	40,000	-
51	NN-2613S	180804C	720,000	720,000	-
52	NN2125R	180804C	310,000	310,000	-
53	NN1825R	180804C	120,000	120,000	-
54	NN-2613S	180806C	720,000	720,000	-
55	NN-2516R	180807C	681,000	681,000	-
56	NN+2713R	180809C	336,000	336,000	-
57	NN3013R	180810C	330,000	330,000	-
58	100215	180810C	70,000	70,000	-
59	NN+2225R	180810C	72,000	72,000	-
60	NN2325R	180811C	540,000	540,000	-
61	NN2516R	180811C	300,000	300,000	-
62	NN-2719S	180811C	720,000	720,000	-
63	NN-2325R	180813C	720,000	720,000	-
64	100279	180814C	270,000	270,000	-
65	100280	180814C	400,000	400,000	-
66	NN-2525R	180815C	720,000	720,000	-
67	NN-2525R	180816C	546,000	546,000	-
68	NN+2713R	180817C	351,000	351,000	-
69	NN-2719S	180818C	297,000	297,000	-
70	NN-2116R	180818C	150,000	150,000	-
71	NN-2325R	180820C	720,000	720,000	-
72	NN+2516R	180822C	93,000	93,000	-
73	NN+2713R	180822C	231,000	231,000	-
74	NN2125R	180823C	720,000	720,000	-

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Items	Item Code	Lot no.	Produced Qty	Shipped Qty.	TPC Inventory
148	NN-2516R	181019C	228,000	228,000	-
149	NN+2713R	181019C	753,000	753,000	-
150	NN2225R	181022C	360,000	360,000	-
151	NN2025R	181023C	100,000	100,000	-
152	NN2525R	181023C	60,000	60,000	-
153	100211	181023C	210,000	210,000	-
154	NN+2713R	181024C	714,000	714,000	-
155	NN-2613S	181024C	558,000	558,000	-
156	NN+2425R	181030C	333,000	42,000	288,000
157	NN-2325R	181030C	186,000	186,000	-
158	NN-2325R	181102C	489,000	489,000	-
159	NN-2225R	181102C	210,000	210,000	-
160	NN-2325R	181103C	504,000	504,000	-
161	NN+2713R	181105C	483,000	483,000	-
162	NN-2516R	181107C	600,000	600,000	-
163	100279	181108C	290,000	290,000	-
164	NN2025R	181108C	130,000	120,000	10,000
165	NN+2116R	181108C	162,000	-	162,000
166	NN2525R	181108C	90,000	90,000	-
167	NN-2325R	181109C	411,000	411,000	-
168	NN2125R	181110C	330,000	330,000	-
169	100220	181110C	360,000	360,000	-
170	NN-2325R	181112C	717,000	510,000	207,000
171	NN3013R	181113C	270,000	270,000	-
172	NN2125R	181113C	370,000	370,000	-
173	NN-2516R	181114C	393,000	393,000	-
174	NN-2719S	181114C	303,000	180,000	123,000
175	100280	181115C	330,000	320,000	10,000
176	NN2325R	181115C	110,000	100,000	10,000
177	NN+2516M	181116C	117,000	-	114,000
178	NN-2725R	181116C	108,000	108,000	-
179	NN+2325M	181116C	99,000	99,000	-
180	NN-2116R	181116C	105,000	105,000	-
181	NN+2519R	181116C	108,000	108,000	-
182	NN-2425R	181116C	189,000	189,000	-
183	NN2516R	181126C	800,000	800,000	-
184	NN+2516R	181126C	654,000	-	642,000
185	NN2125R	181127C	800,000	800,000	-
186	NN2125R	181128C	630,000	630,000	-
187	NN+2125R	181201C	150,000	-	150,000
188	NN+2613R	181203C	720,000	210,000	510,000
189	NN1825R	181204C	520,000	10,000	510,000
190	100204	181204C	320,000	240,000	80,000
191	NN2325R	181204C	100,000	-	100,000
192	NN-2225R	181205C	549,000	93,000	456,000
193	NN-2325R	181205C	261,000	-	261,000
194	NN-2216R	181205C	60,000	60,000	-
195	NN+2516R	181207C	180,000	36,000	144,000
196	NN+2425R	181210C	126,000	-	126,000
197	NN+2525R	181210C	564,000	-	564,000
198	NN+2713R	181210C	720,000	66,000	654,000
199	NN+2713R	181212C	738,000	-	738,000
200	NN2125R	181213C	660,000	360,000	300,000
201	NN+2325R	181213C	276,000	-	276,000
202	100215	181214C	280,000	-	280,000
203	NN+2225R	181214C	162,000	-	162,000
204	NN+2025M	181214C	111,000	-	111,000
205	100204	181215C	80,000	-	80,000
206	100279	181215C	170,000	-	160,000
207	NN+2125R	181215C	207,000	-	207,000
<b>TOTAL</b>			<b>74,555,000</b>	<b>66,536,000</b>	<b>7,951,000</b>

Prepared by:

[Redacted Signature]

Carmen Palos  
Planning Asst. Mgr.

Checked by:

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Maria Victoria Hibalero  
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Approved by:

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Meria Panganiban  
DS Asst. Mgr.