



## URGENT FIELD SAFETY NOTICE

### NIM Flex™ EMG Endotracheal Tube

REF #'s: 8229960, 8229965, 8229970, 8229975, 8229980, 8229985

Lot #'s: see Attachment 1

### RECALL

#### Medtronic Reference: FA571

May 6, 2013

Dear Healthcare Professional (Physician, Hospital Administrator, OR Manager, and Risk Manager),

This letter is to inform you of a voluntary recall of the NIM Flex™ EMG Endotracheal Tube (Flex Tube).

#### Issue Description:

Our tube supplier has advised us that their tubes, used to manufacture the NIM Flex™ Endotracheal Tube product, may have the potential to delaminate. Our investigation has shown that such delamination can result in herniation of the inner lumen when the cuffs are over-inflated. Such herniation can constrict the inner lumen of the endotracheal tube resulting in a reduction of airflow to the patient.

Our records show that you were shipped affected product. We request your assistance by returning any affected devices that you may still have in your stock per the following procedure:

#### Action Requested:

1. Check your inventories for the affected products.
2. If you have any of the subject product, contact Medtronic ENT Customer Service at **AL FAISALIAH MEDICAL SYSTEMS LTD. at +966 1 211 4607**

Your Sales Representative will be contacting you to facilitate the return of any affected NIM Flex™ EMG Endotracheal Tube you may have.

The Competent Authorities of your country has been notified of this action.

Please share this notification with others in your organization as appropriate.

Medtronic ENT regrets any inconvenience this matter may cause; however, we want to make sure that the products we provide to you are of the highest quality and reliability. We therefore ask for your cooperation in helping us to complete this product correction.

Please do not hesitate to contact your Medtronic Sales Representative at **AL FAISALIAH MEDICAL SYSTEMS LTD. at +966 1 211 4607** if you have any questions regarding the subject action or the content of this letter.

Sincerely,

*Salim Hammoud*

*Sr. Business Manager, MEA*

*Surgical Technologies*

#	Lot No.
1	0205255342
2	0205260104
3	0205267294
4	0205268282
5	0205277406
6	0205278364
7	0205285212
8	0205286265
9	0205296649
10	0205306232
11	0205317181
12	0205339172
13	0205339532
14	0205339534
15	0205354917
16	0205356301
17	0205359648
18	0205359652
19	0205383747
20	0205395203
21	0205395369
22	0205395803
23	0205396458
24	0205404191
25	0205407939
26	0205410701
27	0205424594
28	0205424639
29	0205430915
30	0205439551
31	0205446167
32	0205452651
33	0205455531
34	0205469529
35	0205475776
36	0205477245
37	0205480849
38	0205481320
39	0205484371
40	0205488677
41	0205494747
42	0205497070
43	0205498907
44	0205500856
45	0205506056
46	0205506520

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49	0205517780
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51	0205530518
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57	0205539908
58	0205540943
59	0205541565
60	0205547920
61	0205549724
62	0205551946
63	0205557135
64	0205566236
65	0205581241
66	0205588087
67	0205588266
68	0205588562
69	0205588564
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71	0205596483
72	0205610768
73	0205611291
74	0205612769
75	0205613586
76	0205613731
77	0205615348
78	0205616421
79	0205619117
80	0205620410
81	0205621413
82	0205621671
83	0205621746
84	0205623839
85	0205628520
86	0205629779
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89	0205641475
90	0205646468
91	0205646469
92	0205652502

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102	0205689888
103	0205692392
104	0205692393
105	0205692601
106	0205695290
107	0205695322
108	0205708745
109	0205709194
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111	0205713867
112	0205713868
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117	0205732187
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125	0205766784
126	0205766787
127	0205766792
128	0205769388
129	0205773560
130	0205780081
131	0205782945
132	0205782947
133	0205782948
134	0205782949
135	0205785197
136	0205788893
137	0205790787
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142	0205837656
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151	0205891389
152	0205893917
153	0205893987
154	0205893992
155	0205897063
156	0205897209
157	0205897324
158	0205916215
159	0205916408
160	0205916409
161	0205916411
162	0205923551
163	0205923571
164	0205935425
165	0205935426
166	0205937415
167	0205941461
168	0205941525
169	0205942510
170	0205942893
171	0205944362
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175	0205947699
176	0205948915
177	0205953528
178	0205953900
179	0205959235
180	0205959410
181	0205961193
182	0205964307
183	0205964970
184	0205974318

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189	0205985187
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192	0205993667
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194	0205998550
195	0205998557
196	0206010834
197	0206014051
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199	0206014157
200	0206014491
201	0206015160
202	0206017977
203	0206022085
204	0206026176
205	0206028752
206	0206031856
207	0206034287
208	0206039297
209	0206052041
210	0206053629
211	0206055551
212	0206056142
213	0206057509
214	0206058150
215	0206058154
216	0206066041
217	0206069848
218	0206069849
219	0206086713
220	0206099522
221	0206103001
222	0206108460
223	0206137744
224	0206145263
225	0206145265
226	0206146035
227	0206154299
228	0206154794
229	0206160445
230	0206172384

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239	0206214761
240	0206215485
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242	0206223422
243	0206223703
244	0206231036
245	0206232289
246	0206232294
247	0206232295
248	0206235485
249	0206243518
250	0206250824
251	0206252961
252	0206253018
253	0206253315
254	0206258444
255	0206261156
256	0206284160
257	0206285871
258	0206298288
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260	0206332909
261	0206332913
262	0206334691
263	0206371267
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265	59737400
266	59737500
267	59737600
268	59737700
269	59737800
270	59814100
271	59814200
272	59848300
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287	60605100
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293	60735800
294	60735900
295	60736000
296	60855900
297	60856000
298	60856100
299	60915300
300	60915400
301	60915500
302	61072100
303	61072300
304	61072400
305	61072500
306	61072700
307	61211700
308	61211800
309	61211900
310	61320200
311	61343100
312	61343200
313	61343300
314	61343400
315	61343500
316	61445700
317	61468200
318	61468300
319	61489900
320	61490000
321	61490100
322	61490200

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324	61544600
325	61578100
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327	61671400
328	61671500
329	61671600
330	61671700
331	61695800
332	61696000
333	61740900
334	61741000
335	61741100
336	61741200
337	61741300
338	61802500
339	61802600
340	61802700
341	61802800
342	61803100
343	61897200
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354	62230900
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356	62290300
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358	62290500
359	62310000
360	62331100
361	62331200
362	62331500
363	62438900
364	62462800
365	62504300
366	62613300
367	62613400
368	62613500

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373	62711700
374	62711800
375	62711900
376	62757600
377	62757700
378	62757800
379	62794500
380	62816600
381	62816700
382	62816800
383	62836900
384	62837000
385	62926400
386	62926500
387	62926600
388	62942300
389	62966300
390	62966400
391	63022200
392	63022300
393	63022400
394	63070300
395	63070700
396	63089000
397	63181900
398	63182100
399	63198700
400	63198900
401	63314900
402	63315100
403	63377600
404	63394400
405	63394500
406	63506700
407	63507200
408	63619300
409	63619400
410	63619700
411	63670100
412	63708900
413	63709600
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418	63830800
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421	63991500
422	63991600
423	64013100
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425	64013600
426	64035500
427	64035600
428	64139100
429	64139200
430	64139300
431	64374500
432	64478400
433	64478500
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436	64595900
437	64596400
438	64640200
439	64640300
440	64640400
441	64640500
442	64640600
443	64681500
444	64681600
445	64701400
446	64732300
447	64732400
448	64763900
449	64764000
450	64764800
451	64764900
452	64765000
453	64843300
454	64872200
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456	64915600
457	64973700
458	64973800
459	64973900
460	64974000

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466	65056300
467	65118300
468	65118400
469	65118500
470	65118600
471	65131400
472	65173900
473	65174000
474	65260100
475	65260200
476	65260400
477	65290900
478	65291000
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481	65362900
482	65531300
483	65531500
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493	65675000
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495	65675200
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497	65713800
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504	65894600
505	65914500
506	65982800

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514	66201500
515	66201600
516	66201700
517	66201800
518	66201900
519	66249700
520	66321800
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522	66383800
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524	66384300
525	66452200
526	66452400
527	66452500
528	66452600
529	66492500
530	66512400
531	66584300
532	66604900
533	66605000
534	66605100
535	66605200
536	66661000
537	66661200
538	66661500
539	66679100
540	66679500
541	66713100
542	66729400
543	66729700
544	66811000
545	66811400
546	66811500
547	66811600
548	66855600
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550	66855800
551	67023200
552	67088300

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557	67113600
558	67211700
559	67211800
560	67211900
561	67212000
562	67212100
563	67212200
564	67258500
565	67276400
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571	67411700
572	67411800
573	67469700
574	67502400
575	67530100
576	67530200
577	67530300
578	67538300
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581	67677300
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586	67713800
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589	67725900
590	67726000
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592	67821500
593	67836700
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622	68258900
623	68277700
624	68288000
625	68288100
626	68369400
627	68369500
628	68369600
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635	68495900
636	68496500
637	68534900
638	68535000
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643	68821300
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673	69469400
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675	69556000
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678	69580700
679	69580800
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707	70021500
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710	70070400
711	70070500
712	70070600
713	70070800
714	70070900
715	70094500
716	70114500
717	70114600
718	70114700
719	70114800
720	70202600
721	70202700
722	70244700
723	70244800
724	70267800
725	70267900
726	70268100
727	70340400
728	70340500
729	70340600
730	70363300
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732	70363700
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745	70534400
746	70564200
747	70564300
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752	70583100
753	70597000
754	70614600
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756	70641400
757	70641600
758	70672000
759	70709400
760	70709900
761	70710200
762	70756200
763	70792100
764	70792200
765	70792300
766	70792400
767	70792600
768	70838500
769	70838600
770	70838700
771	70838800
772	70859400
773	70859900
774	70924900
775	70925000
776	70963200
777	70987000
778	70987100
779	70987200
780	71004200
781	71021500
782	71074200

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790	71180200
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792	71180500
793	71180600
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796	71222100
797	71222200
798	71222300
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803	71287900
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805	71305400
806	71317700
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808	71353300
809	71430900
810	71431000
811	71431300
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813	71447800
814	71464200
815	71487700
816	71487800
817	71505600
818	71527500
819	71531700
820	71532000
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822	71555700
823	71579200
824	71579300
825	71579400
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837	71745600
838	71745700
839	71747000
840	71749000
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842	71749200
843	71749300
844	71749400
845	71749500
846	71781600
847	71781700
848	71781800
849	71781900
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852	71866700
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854	71883400
855	71886500
856	71886600
857	71904400
858	71904500
859	71904600
860	71905300
861	71925500
862	71925600
863	71990800
864	71990900
865	71991000
866	71991100
867	72031200
868	72031300
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872	72089000
873	72089100
874	72089200

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879	72093200
880	72093300
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883	72109400
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887	72185500
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889	72229300
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892	72251000
893	72251100
894	72284100
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897	72301400
898	72309400
899	72309500
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901	72321500
902	72321600
903	72333300
904	72333400
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906	72334100
907	72334200
908	72357100
909	72415700
910	72418600
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912	72462300
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914	72523300
915	72523800
916	72563500
917	72563600
918	72563700
919	72639200
920	72639300

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925	72649800
926	72650000
927	72674700
928	72696200
929	72697100
930	72721400
931	72721500
932	72727900
933	72740800
934	72740900
935	72741000
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937	72741200
938	72758700
939	72760200
940	72760300
941	72782700
942	72782900
943	72783000
944	72801000
945	72865800
946	72866400
947	72866500
948	72903000
949	72903100
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951	72920100
952	72920200
953	72920300
954	72956200
955	73033700
956	73049400
957	73061400
958	73061500
959	73061600
960	73061700
961	73061800
962	73061900
963	73074800
964	73134600
965	73147800
966	73177900

#	Lot No.
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968	73178100
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970	73214000
971	73214100
972	73246100
973	73248500
974	73266400
975	73318400
976	73334200
977	73360700
978	73368500
979	73368600
980	73374400
981	73404400
982	73423600
983	73425300
984	73437900
985	73457900
986	73458000
987	73472100
988	73472200
989	73472300
990	73515300
991	73533100
992	73544600
993	73547400
994	73561900
995	73600900
996	73601000
997	73606700
998	73608300
999	73608400
1000	73608500
1001	73627700
1002	73627800
1003	73660200
1004	73661000
1005	73716400
1006	73722900
1007	73723000
1008	73730000
1009	73742000
1010	73826600

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