

**URGENT FIELD SAFETY NOTICE**

**Custom Procedure kits containing certain production lots of Clearify™ Visualization System**

October 26th, 2016

**Attention: Risk Management Director and OR Materials Management  
Please forward this communication to all surgeons, surgical personnel, and any other potential users of the product.**

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is recalling specific production lots of item code 21-345, Clearify™ visualization system, which are included in Custom Procedure kits that have been shipped to your facility.

This Field Safety Corrective Action (FSCA) is being conducted due to the potential for compromise of the package resulting in a breach of the sterile barrier. There have been no reports of serious injury associated with this issue, but use of products with this packaging defect may increase risk of infection.

Medtronic requests that you quarantine and return any unused Custom Procedure kits listed in attachment A. Affected kit codes that are unused should be returned as described in the "Required Actions" section below. If you have distributed the Custom Procedure kits that contain Clearify™ visualization system products listed below, please promptly forward the information from this letter to those recipients. **All affected kits must be returned.**

This action is being taken with the knowledge of your local Competent Authority. We request that you contact Medtronic if you experienced quality problems or adverse events.

Email Medtronic Regulatory Affairs at: XXXXX@Medtronic.com

**REQUIRED ACTIONS:**

1. Please quarantine and discontinue use of the affected products listed above.
2. Please return affected product as follows:

	<b>Customer with inventory:</b>	<b>Customer with zero inventory</b>	<b>Where to send the completed form</b>
Purchased <b>directly</b> from	Please complete the attached Returns	Complete form and check the	E-mail or fax the completed form to

<p>Medtronic</p>	<p>Verification Form in its entirety. Upon receiving your form, Medtronic Customer Care will contact you to organize the return of your products. You will receive credit for unused device(s) that you return.</p>	<p>box indicating "no inventory"</p>	<p>the Medtronic contact provided on the verification form.</p>
<p>Purchased from a <b>distributor</b></p>	<p>Complete <b>all</b> fields on the form and contact your distributor directly to arrange for return of product</p>	<p>Complete form and check the box indicating "no inventory"</p>	<p>E-mail or fax the completed form to your Distributor &amp; to the Medtronic contact provided on the verification form.</p>

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative at (xxx) xxx-xxxx.



Sincerely,  
 J. Bryan Dannettell  
 Vice President, Quality Assurance  
 Surgical Innovations  
 Medtronic

## ATTACHMENT A

Kit Order Nr or Lot No	Kit Code	Item Code	Lot Number
0591666	KIT002006URO3CL	21-345	0591666
0593770	KIT014005OMEGA0	21-345	0593770
0597623	KIT014005COLID0	21-345	0597623
0597625	KIT014005OMEGA0	21-345	0597625
0597538	KIT002006URO3CL	21-345	0597538
0600396	KIT014005COLID0	21-345	0600396
0601141	KIT002006URO3CL	21-345	0601141
0604367	KIT002006URO3CL	21-345	0604367
0607170	KIT014005OMEGA1	21-345	0607170
0610428	KIT014005OMEGA1	21-345	0610428
0606961	KIT002006URO5CL	21-345	0606961
0613248	KIT002006URO5CL	21-345	0613248
6138861930	KIT014005OMEGA2 BBR SLBG OMEGA LOOPKIT	21-345	211759226
6137955375	KIT002006URO5CL 002006 BBR ACCURO	21-345	211537638
6137540456	KIT002006URO5CL 002006 BBR ACCURO	21-345	211452390
0974277	K-BE-COL200-200	21-345	0974277
0970570	K-BE-VATS80-801	21-345	0970570
0980113	K-BE-BAR231-231	21-345	0980113
0980201	K-BE-VATS80-801	21-345	0980201
0975729	K-BE-BAR231-231	21-345	0975729
0981931	K-BE-BAR231-231	21-345	0981931
0979449	K-BE-CAR100-100	21-345	0979449
0976886	K-BE-BAR231-231	21-345	0976886
0983334	K-BE-CAR100-100	21-345	0983334
0987078	K-BE-VATS80-801	21-345	0987078
0987647	K-BE-BAR231-231	21-345	0987647
0984895	K-BE-COL200-200	21-345	0984895
0985236	K-BE-CAR100-100	21-345	0985236
0985701	K-BE-BAR231-231	21-345	0985701
0990143	KURO100	21-345	0990143
0988558	K-BE-BAR231-231	21-345	0988558
0990949	K-BE-VATS80-801	21-345	0990949
0991824	K-BE-COL200-200	21-345	0991824
0991946	K-BE-COL200-200	21-345	0991946
0989568	K-BE-CAR100-100	21-345	0989568

0990949	K-BE-VATS80-801	21-345	0990949
0992254	KBAR231	21-345	0992254
0996392	K-BE-CAR100-100	21-345	0996392
0993306	KBAR231	21-345	0993306
0993659	KBAR231	21-345	0993659
0994454	K-BE-CAR100-100	21-345	0994454
6138237436	K-BE-CAR100-100 KIT CARDIO 100 X1	21-345	211600067
6138897638	KBAR231 BAR SLEEVE 231 X1	21-345	211743859
6138465944	KBAR231 BAR SLEEVE 231 X1	21-345	211652597
6138018965	KVATS801 THORACIC VATS 800 X1	21-345	211552267
6137196467	KVATS801 THORACIC VATS 800 X1	21-345	211359522
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0181621	KIT2912A	21-345	0181621
0184561	KIT2951V	21-345	0184561
0185020	KIT2951V	21-345	0185020
0186059	KIT2951V	21-345	0186059
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0187375	KIT2106A	21-345	0187375
0187739	KIT2964A	21-345	0187739
0189591	KIT2912A	21-345	0189591
0189838	KIT2951V	21-345	0189838
6138064030	BOX KIT2912B NEPHRECTOMY KIT	21-345	211555769
6137960865	KIT2960 LAP HERNIE PARIETEX X1	21-345	211537531
0118899	KIT3049C	21-345	0118899
0118283	KIT3049C	21-345	0118283
0118227	KIT3049C	21-345	0118227
0118867	KIT3063	21-345	0118867
0118226	KIT3074	21-345	0118226
0118485	KIT3074	21-345	0118485
0118520	KIT3084	21-345	0118520
0118576	KIT3085	21-345	0118576
0118899	KIT3049C	21-345	0118899
0120426	KIT3085	21-345	0120426
0119095	KIT3073A	21-345	0119095
0120323	KIT3049C	21-345	0120323
0120721	KIT3073A	21-345	0120721
0121870	KIT3073A	21-345	0121870
0121141	KIT3049C	21-345	0121141
0121058	KIT3084	21-345	0121058

0121745	KIT3049C	21-345	0121745
0121870	KIT3073A	21-345	0121870
0122452	KIT3074	21-345	0122452
0122125	KIT3086	21-345	0122125
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0122126	KIT3087	21-345	0122126
0122152	KIT3049C	21-345	0122152
0122297	KIT3073A	21-345	0122297
0123798	KIT3074	21-345	0123798
0123797	KIT3049C	21-345	0123797
0123900	KIT3095	21-345	0123900
0123907	KIT3096	21-345	0123907
0123876	KIT3073A	21-345	0123876
0122979	KIT3084	21-345	0122979
0124048	KIT3049C	21-345	0124048
0124081	KIT3049C	21-345	0124081
0124050	KIT3074	21-345	0124050
0124133	KIT3074	21-345	0124133
0123411	KIT3074	21-345	0123411
0122980	KIT3085	21-345	0122980
0123400	KIT3094	21-345	0123400
0123414	KIT3092	21-345	0123414
0123618	KIT3096	21-345	0123618
0123552	KIT3086	21-345	0123552
0123553	KIT3087	21-345	0123553
0124133	KIT3074	21-345	0124133
0124133	KIT3074	21-345	0124133
0124323	KIT3073A	21-345	0124323
0124479	KIT3088	21-345	0124479
6137502747	KIT3049C PEIJAS BY-PASS KIT X1	21-345	211439351
6137533175	KIT3049C PEIJAS BY-PASS KIT X1	21-345	211444522
6138039839	KIT3049C PEIJAS BY-PASS KIT X1	21-345	211551419
6137920683	KIT3095 JORVI 5MM TROAKAARI KIT X1	21-345	211679782
6137465204	KIT3088 SAIPA1948 X1	21-345	211433243
4214040	KIT-DE-0070	21-345	4214040
4214040	KIT-DE-0070	21-345	4214040
4214044	KIT-DE-0073	21-345	4214044
4237449	KIT-DE-0072V	21-345	4237449
4248472	KIT-DE-0069	21-345	4248472

4248476	KIT-DE-0073	21-345	4248476
4234136	KIT-DE-0070	21-345	4234136
4272167	KIT-DE-0072V	21-345	4272167
4272165	KIT-DE-0070	21-345	4272165
4279618	KIT-DE-0073	21-345	4279618
4279613	KIT-DE-0071	21-345	4279613
4289045	KIT-DE-0072V	21-345	4289045
6137647370	KIT-DE-0073 TROKAR KIT 5MM AUG KOLNX1	21-345	211480362
6138596899	KIT-DE-0073 TROKAR KIT 5MM AUG KOLNX1	21-345	211682529
6137647370	KIT-DE-0070 TROKAR KIT 11MM AUG KOLN X1	21-345	211480360
6138596899	KIT-DE-0070 TROKAR KIT 11MM AUG KOLN X1	21-345	211682528
6138191208	KIT-DE-0069 TROKAR KIT 12 AUG KOLNX1	21-345	211594620
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0092501	LOUTHCOLAPCHOLE	21-345	0092501
0093712	LOUTHCOLAPCHOLE	21-345	0093712
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0095020	LOUTHCOLAPCHOLE	21-345	0095020
0096452	LOUTHCOLAPCHOLE	21-345	0096452
6138861705	BOX LOUHLAPCHOLE5 LOUHL COUNTY LAP 5MM	21-345	211757527
6138804228	BOX LOUHLAPCHOLE10 LOUHL LAP CHOLE 10MM	21-345	211719278
6137501703	LOUTHCOLAPCHOLE LOUHL CO LAP CHOLE KIT	21-345	211440107
1782005	KIT-LA0583	21-345	1782005
1780458	KIT-LA0588	21-345	1780458
1782155	KIT-LA0584	21-345	1782155
1796089	KIT-LA0584	21-345	1796089
1799754	KIT-LA0613	21-345	1799754
1811755	KIT-LA0584	21-345	1811755
1813755	KIT-LA0583	21-345	1813755
1831657	KIT-LA0584	21-345	1831657
1832360	KIT-LA0584	21-345	1832360
1830055	KIT-LA0584	21-345	1830055
1824301	KIT-LA0584	21-345	1824301
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6138340920	KIT-LA0583 KIT-LA0583 KIT X1	21-345	211621866
6137880269	KIT-LA0584 KIT-LA0584 KIT X1	21-345	211522545
6137692148	KIT-LA0584 KIT-LA0584 KIT X1	21-345	211485646

6137535926	KIT-LA0584 KIT-LA0584 KIT X1	21-345	211443529
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6137203000	KGYN100 GYN GENERAL 100 X1	21-345	211370120
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0168546	KIT4253	21-345	0168546
6137683540	KIT4253 LAP GASTRIC BYPASS KIT X1	21-345	211484770
6138723265	KIT4253 LAP GASTRIC BYPASS KIT X1	21-345	211706865
6138723265	KIT4252 LAP SLEEVE GASTRECTOMY KIT X1	21-345	211706866
0543648	LAPPOL1C	21-345	0543648
0541090	BARBYPASSEGIA48	21-345	0541090
0543334	LAPBARI	21-345	0543334
0541969	LAPPOL1C	21-345	0541969
0549302	LAPPOL1C	21-345	0549302
0549334	LAPBARI	21-345	0549334
0552151	LAPPOL1C	21-345	0552151
0551385	SZCZVATS	21-345	0551385
0551379	BARSLEEVEEGIA	21-345	0551379
0551380	BARBYPASSEGIA48	21-345	0551380
0551383	COLEGIA28	21-345	0551383
0551384	COLEGIA31	21-345	0551384

0551382	BARBYPASSEGIA35	21-345	0551382
0546466	LAPPOL1C	21-345	0546466
0546472	LAPPOL1C	21-345	0546472
0552151	LAPPOL1C	21-345	0552151
0555674	LAPPOL1C	21-345	0555674
0554230	LAPBARI	21-345	0554230
0556451	LAPBARI	21-345	0556451
0554165	SZCZVATS	21-345	0554165
0554164	COLEGIA31	21-345	0554164
0554168	COLEGIA28	21-345	0554168
0556574	LAPPOL1C	21-345	0556574
0560616	COLEGIAM28	21-345	0560616
0560617	COLEGIAM31	21-345	0560617
0558929	SZCZVATS	21-345	0558929
0560508	SZCZVATS	21-345	0560508
0561553	LAPPOL1C	21-345	0561553
0562596	BARSLEEVEEGIA	21-345	0562596
0560509	BARBYPASSEGIA35	21-345	0560509
0560510	BARBYPASSEGIA48	21-345	0560510
0559678	BARSLEEVE	21-345	0559678
0559680	COLIDRIVE28	21-345	0559680
0559683	COLIDRIVE31	21-345	0559683
0559684	COLEGIA31	21-345	0559684
0559679	BARBYPASS35	21-345	0559679
0559676	BARBYPASS48	21-345	0559676
0560508	SZCZVATS	21-345	0560508
0563872	SZCZVATS	21-345	0563872
0564441	LAPPOL6C	21-345	0564441
0563875	BARBYPASSEGIA48	21-345	0563875
0568158	LAPPOL1C	21-345	0568158
0567092	LAPPOL4CI	21-345	0567092
0564440	LAPPOL5C	21-345	0564440
0566080	LAPPOL1C	21-345	0566080
0565268	BARBYPASS35	21-345	0565268
0565270	BARBYPASS48	21-345	0565270
0567859	LAPPOL7C	21-345	0567859
0569547	SZCZVATS	21-345	0569547
0569070	BARSLEEVEEGIA	21-345	0569070
6138136137	LAPPOL1C ZESTAW DO CHOLECYSTEKTOMIIX1	21-345	211569812



6137198795	LAPPOL1C ZESTAW DO CHOLECYSTEKTOMIIX1	21-345	211359765
6138373954	LAPPOL5C ZESTAW CHOLE X1	21-345	211627745
6137731052	LAPPOL5C ZESTAW CHOLE X1	21-345	211497216
6138764092	LAPPOL1C ZESTAW DO CHOLECYSTEKTOMIIX1	21-345	211712983
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6138643270	BOX PST00611 KITBYPASSIIFARMACOR	21-345	211702967
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2260473	KIT00523	21-345	2260473
2275954	KIT00375R-1	21-345	2275954
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2260661	KIT00536C	21-345	2260661
2264790	KIT00393R-1	21-345	2264790
2275953	KIT00169R-1	21-345	2275953
2264790	KIT00393R-1	21-345	2264790
2265235	KIT00540C	21-345	2265235
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2265609	KIT00569B	21-345	2265609
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2271979	KIT00540C	21-345	2271979
2273452	KIT00540C	21-345	2273452
2274356	KIT00540C	21-345	2274356
2271625	KIT00536C	21-345	2271625
2255537	KIT00393R-1	21-345	2255537
2255609	KIT00375R	21-345	2255609
2255617	KIT00539	21-345	2255617
2255604	KIT00214R	21-345	2255604
2257252	KIT00269R	21-345	2257252
2255408	KIT00011C	21-345	2255408
2257134	KIT00587	21-345	2257134
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2259125	KIT00542	21-345	2259125
2267931	KIT00570B-1	21-345	2267931
2266921	KIT00517A	21-345	2266921
2266928	KIT00517A	21-345	2266928
2267176	KIT00396R	21-345	2267176

2275028	KIT00393R-1	21-345	2275028
2269413	KIT00269R-1	21-345	2269413
2276888	KIT00214R	21-345	2276888
2268600	KIT00574	21-345	2268600
2293169	KIT00589R	21-345	2293169
2297128	KIT00011C	21-345	2297128
2293689	KIT00142C1	21-345	2293689
2292832	KIT00393R-1	21-345	2292832
2296786	KIT00313C	21-345	2296786
2295688	KIT00269R-1	21-345	2295688
2278323	KIT00519C	21-345	2278323
2277591	KIT00269R-1	21-345	2277591
2277923	KIT00375R-1	21-345	2277923
2276888	KIT00214R	21-345	2276888
2277136	KIT00142C	21-345	2277136
2278785	KIT00542	21-345	2278785
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2297175	KIT00214R	21-345	2297175
2291016	KIT00375R-1	21-345	2291016
2287191	KIT00269R-1	21-345	2287191
2297586	KIT00142C1	21-345	2297586
2291432	KIT00011C	21-345	2291432
2297128	KIT00011C	21-345	2297128
2288202	KIT00589R	21-345	2288202
2296882	KIT00589R	21-345	2296882
2291541	KIT00569B-1	21-345	2291541
2298519	KIT00542V	21-345	2298519
2286744	KIT00587	21-345	2286744
2280907	KIT00540C	21-345	2280907
2283419	KIT00569B-1	21-345	2283419
2283568	KIT00142C	21-345	2283568
2291432	KIT00011C	21-345	2291432
2280377	KIT00536C	21-345	2280377
2280577	KIT00187R-1	21-345	2280577
2282548	KIT00396R	21-345	2282548
2279013	KIT00449	21-345	2279013
2280367	KIT00536C	21-345	2280367
2303025	KIT00375R-1	21-345	2303025
2302067	KIT00142C1	21-345	2302067

2303742	KIT00559	21-345	2303742
2304463	KIT00542V	21-345	2304463
2304820	KIT00540C	21-345	2304820
2305716	KIT00449	21-345	2305716
2305606	KIT00536C	21-345	2305606
2305614	KIT00536C	21-345	2305614
2307933	KIT00517A	21-345	2307933
2308578	KIT00517A	21-345	2308578
2310571	KIT00269R-1	21-345	2310571
2305716	KIT00449	21-345	2305716
2308486	KIT00336A	21-345	2308486
2309120	KIT00519C	21-345	2309120
2308653	KIT00542V	21-345	2308653
2308040	KIT00569B-1	21-345	2308040
2306286	KIT00142C1	21-345	2306286
2307933	KIT00517A	21-345	2307933
2323274	KIT00536CV	21-345	2323274
2326563	KIT00119R	21-345	2326563
2317305	KIT00540C	21-345	2317305
2314529	KIT00589R	21-345	2314529
2313025	KIT00542V	21-345	2313025
2306299	KIT00583V	21-345	2306299
2310581	KIT00142C1	21-345	2310581
2312008	KIT00142C1	21-345	2312008
2310571	KIT00269R-1	21-345	2310571
2311120	KIT00393R-1	21-345	2311120
2311126	KIT00393R-1	21-345	2311126
2311847	KIT00269R-1	21-345	2311847
2315459	KIT00214R	21-345	2315459
2316158	KIT00169R-1	21-345	2316158
2316265	KIT00570B-1	21-345	2316265
2316724	KIT00540C	21-345	2316724
2318359	KIT00583V	21-345	2318359
2319801	KIT00589R	21-345	2319801
2319317	KIT00142C1	21-345	2319317
2323389	KIT00142C1	21-345	2323389
2323956	KIT00169R-1	21-345	2323956
2323954	KIT00375R-1	21-345	2323954
2321202	KIT00269R-1	21-345	2321202

2323283	KIT00536CV	21-345	2323283
2317125	KIT00375R-1	21-345	2317125
2316728	KIT00540C	21-345	2316728
2316724	KIT00540C	21-345	2316724
2317305	KIT00540C	21-345	2317305
2337155	KIT00569B-1	21-345	2337155
2337676	KIT00625R	21-345	2337676
2337051	KIT00627	21-345	2337051
2338620	KIT00602V	21-345	2338620
2336780	KIT00169R-1	21-345	2336780
2338381	KIT00142C1	21-345	2338381
2338749	KIT00393R-1	21-345	2338749
2338750	KIT00393R-1	21-345	2338750
2338829	KIT00214R	21-345	2338829
2326439	KIT00542V	21-345	2326439
2331729	KIT00574	21-345	2331729
2331388	KIT00540C	21-345	2331388
2331112	KIT00540C	21-345	2331112
2330563	KIT00449	21-345	2330563
2327815	KIT00393R-1	21-345	2327815
2330252	KIT00313V1	21-345	2330252
2327804	KIT00375R-1	21-345	2327804
2354524	KIT00540C	21-345	2354524
2329930	KIT00626	21-345	2329930
2330371	KIT00542V	21-345	2330371
2327631	KIT00142C1	21-345	2327631
2330945	KIT00011C	21-345	2330945
2342467	KIT00142C1	21-345	2342467
2345645	KIT00540C	21-345	2345645
2342244	KIT00375R-1	21-345	2342244
2338829	KIT00214R	21-345	2338829
2338850	KIT00170R-1	21-345	2338850
2336324	KIT00517A	21-345	2336324
2331729	KIT00574	21-345	2331729
2339168	KIT00542V	21-345	2339168
2336324	KIT00517A	21-345	2336324
2336327	KIT00517A	21-345	2336327
2338979	KIT00336A	21-345	2338979
2329047	KIT00519C	21-345	2329047

2333628	KIT00269R-1	21-345	2333628
2333626	KIT00269R-1	21-345	2333626
2332276	KIT00269R-1	21-345	2332276
2332895	KIT00542V	21-345	2332895
2331729	KIT00574	21-345	2331729
2332789	KIT00142C1	21-345	2332789
2331463	KIT00574	21-345	2331463
2349905	KIT00214R	21-345	2349905
2350206	KIT00540C	21-345	2350206
2349307	KIT00520C	21-345	2349307
2350526	KIT00536CV	21-345	2350526
2346308	KIT00449	21-345	2346308
2350206	KIT00540C	21-345	2350206
2350093	KIT00269R2	21-345	2350093
2359631	KIT00168R-1	21-345	2359631
2359648	KIT00569B-1	21-345	2359648
2359883	KIT00633	21-345	2359883
2359109	KIT00589RV	21-345	2359109
2362799	KIT00269R2	21-345	2362799
2360686	KIT00375R2	21-345	2360686
2360298	KIT00269R-1	21-345	2360298
2360142	KIT00523V	21-345	2360142
2359982	KIT00396RV	21-345	2359982
2348418	KIT00517A	21-345	2348418
2348422	KIT00517A	21-345	2348422
2349505	KIT00313V1	21-345	2349505
2349905	KIT00214R	21-345	2349905
2345871	KIT00624	21-345	2345871
2341452	KIT00633	21-345	2341452
2349312	KIT00583V	21-345	2349312
2348277	KIT00576-1	21-345	2348277
2349500	KIT00142C1	21-345	2349500
2363073	KIT00142C1	21-345	2363073
2364761	KIT00169R-1	21-345	2364761
2365618	KIT00517A	21-345	2365618
2365256	KIT00336A	21-345	2365256
2365612	KIT00336A	21-345	2365612
2364663	KIT00449	21-345	2364663
2360686	KIT00375R2	21-345	2360686

2365333	KIT00520C	21-345	2365333
2354058	KIT00393R-1	21-345	2354058
2354063	KIT00393R-1	21-345	2354063
2365618	KIT00517A	21-345	2365618
2365623	KIT00517A	21-345	2365623
2355658	KIT00269R2	21-345	2355658
2355654	KIT00375R2	21-345	2355654
2354524	KIT00540C	21-345	2354524
2366675	KIT00142C1	21-345	2366675
2355224	KIT00589R	21-345	2355224
2365873	KIT00625	21-345	2365873
2345865	KIT00623	21-345	2345865
2334503	KIT00589R	21-345	2334503
2346588	KIT00011C	21-345	2346588
2346599	KIT00011C	21-345	2346599
2346099	KIT00169R-1	21-345	2346099
2345645	KIT00540C	21-345	2345645
2345814	KIT00269R-1	21-345	2345814
2346465	KIT00269R-1	21-345	2346465
2346218	KIT00187R-1	21-345	2346218
2345861	KIT00396R	21-345	2345861
2354035	KIT00393R-1	21-345	2354035
2354043	KIT00393R-1	21-345	2354043
2354049	KIT00393R-1	21-345	2354049
2350534	KIT00536CV	21-345	2350534
2352101	KIT00375R2	21-345	2352101
2353292	KIT00269R2	21-345	2353292
2354080	KIT00214R	21-345	2354080
2352502	KIT00627	21-345	2352502
2354691	KIT00587	21-345	2354691
2355858	KIT00540C	21-345	2355858
2356124	KIT00142C1	21-345	2356124
2355658	KIT00269R2	21-345	2355658
2350526	KIT00536CV	21-345	2350526
2370120	KIT00540C	21-345	2370120
2368353	KIT00587V	21-345	2368353
2369740	KIT00542V	21-345	2369740
2368027	KIT00570B-1	21-345	2368027
2371822	KIT00570B-1	21-345	2371822

2367592	KIT00569B-1	21-345	2367592
2369438	KIT00569B-1	21-345	2369438
2371827	KIT00396RV	21-345	2371827
2369496	KIT00269R-1	21-345	2369496
2367907	KIT00375R2	21-345	2367907
2367727	KIT00269R2	21-345	2367727
2369265	KIT00269R2	21-345	2369265
2367593	KIT00169R-1	21-345	2367593
	KIT00269R-1 APENDICECTOMIA LAPAROSCOPICA	21-345	211712433
6138762175			
6137775298	KIT00569B-1 COLECTOMIA IZDA LAP - BX1	21-345	211503718
6137616409	KIT00569B-1 COLECTOMIA IZDA LAP - BX1	21-345	211473608
6138089295	KIT00142C1 COLECISTECTOMIA X1	21-345	211560512
6137967311	KIT00142C1 COLECISTECTOMIA X1	21-345	211561829
6138762992	KIT00583V NEFRECTOMIA X1	21-345	211712810
6137204819	KIT00170R-1 NEFRECTOMIA LAPAROSCOPICA X1	21-345	211369415
6137170183	KIT00519C COLECISTECTOMIA X1	21-345	211353853
6137101905	KIT00313V1 COLON	21-345	211343440
6138896867	KIT00570B-1 RECTO LAP - B X1	21-345	211744868
6137101905	KIT00313V1 COLON	21-345	211373302
6138132316	KIT00142C1 COLECISTECTOMIA X1	21-345	211566218
6137513810	KIT00169R-1 QUISTECTOMIA LAPAROSCOPICA	21-345	211440104
6138273424	KIT00313V1 COLON	21-345	211605159
6137089007	KIT00542V GASTRECTOMIA TUBULAR II X1	21-345	211341905
6137154471	KIT00542V GASTRECTOMIA TUBULAR II X1	21-345	211352384
6138379925	KIT00542V GASTRECTOMIA TUBULAR II X1	21-345	211627975
6138531880	KIT00542V GASTRECTOMIA TUBULAR II X1	21-345	211670646
6138158580	KIT00169R-1 QUISTECTOMIA LAPAROSCOPICA	21-345	211586263
6137162180	KIT00142C1 COLECISTECTOMIA X1	21-345	211352903
6137162180	KIT00142C1 COLECISTECTOMIA X1	21-345	211439308
6137240450	KIT00576-1 HISTERECTOMY & LINFADENECTOMY	21-345	211384510
6137392304	KIT00519C COLECISTECTOMIA X1	21-345	211437932
6138608943	KIT00633 COLON X1	21-345	211683963
6138125806	KIT00633 COLON X1	21-345	211566206
6137308711	KIT00634 COLECISTECTOMIA X1	21-345	211399181
6138853395	KIT00269R2 APENDICECTOMIA LAPAROSSOPICA	21-345	211730828
6138493622	KIT00269R2 APENDICECTOMIA LAPAROSSOPICA	21-345	211657139
6138352502	KIT00269R2 APENDICECTOMIA LAPAROSSOPICA	21-345	211637009
6137616422	KIT00269R2 APENDICECTOMIA LAPAROSSOPICA	21-345	211485942
6137237664	KIT00269R2 APENDICECTOMIA LAPAROSSOPICA	21-345	211442942

6138374238	KIT00375R2 COLECISTECTOMIA LAP	21-345	211628777
6138194269	KIT00375R2 COLECISTECTOMIA LAP	21-345	211594764
6138033483	KIT00375R2 COLECISTECTOMIA LAP	21-345	211552577
6137830683	KIT00375R2 COLECISTECTOMIA LAP	21-345	211518524
6137617358	KIT00375R2 COLECISTECTOMIA LAP	21-345	211485943
6137151793	KIT00375R2 COLECISTECTOMIA LAP	21-345	211390646
6137240913	KIT00375R2 COLECISTECTOMIA LAP	21-345	211392917
6137930938	KIT00589RV COLON D.A. X1	21-345	211598737
6137930938	KIT00589RV COLON D.A. X1	21-345	211532571
6137570754	KIT00589RV COLON D.A. X1	21-345	211457895
6138566662	KIT00177RV HERNIA HIATO LAPAROSCOPICA	21-345	211679202
6138184577	KIT00536CV COLECISTECTOMIA S VISUAL	21-345	211592355
6137768920	KIT00214R APENDICECTOMIA X1	21-345	211502358
6138184577	KIT00536CV COLECISTECTOMIA S VISUAL	21-345	211592356
6138349450	KIT00214R APENDICECTOMIA X1	21-345	211623340
6138883232	KIT00626 APENDICECTOMIA X1	21-345	211742840
6138156325	KIT00625 COLON X1	21-345	211576538
6138183856	KIT00627 APENDICECTOMIA X1	21-345	211591090
6137398327	KIT00627 APENDICECTOMIA X1	21-345	211416789
6137831496	KIT00435RV SUPRARENALECTO LAP	21-345	211518281
6138231221	BOX KIT00142CV KIT COLECISTECTOMIA	21-345	211599773
6138154087	KIT00396RV HERNIA LAPAROSCOPICA TEP	21-345	211577190
6137310741	KIT00336A CIRUGIA BARIÁTRICA A X1	21-345	211439316
6138347345	KIT00336A CIRUGIA BARIÁTRICA A X1	21-345	211619119
6137394586	KIT00574 COLECISTECTOMIA X1	21-345	211453122
6138204142	KIT00574 COLECISTECTOMIA X1	21-345	211595343
6137452346	KIT00540C PUNCION BOLSA ENDOC Y ENDOT X1	21-345	211439708
6137836644	KIT00540C PUNCION BOLSA ENDOC Y ENDOT X1	21-345	211517722
6137744048	KIT00540C PUNCION BOLSA ENDOC Y ENDOT X1	21-345	211576557
6138895222	KIT00540C PUNCION BOLSA ENDOC Y ENDOT X1	21-345	211745076
6137997845	KIT00520C COLECISTECTOMIA C. BLADELESS	21-345	211546270
6138307376	KIT00520C COLECISTECTOMIA C. BLADELESS	21-345	211610678
6138416137	KIT00520C COLECISTECTOMIA C. BLADELESS	21-345	211637274
6137451181	KIT00119R COLEC VERSASTEP X1	21-345	211437539
6137283101	KIT00517A KIT COLECISTECTOMIA C.VERRES	21-345	211439315
6137283101	KIT00517A KIT COLECISTECTOMIA C.VERRES	21-345	211439314
6137347998	KIT00449 COLECISTECTOMIA H M & L X1	21-345	211437930
6137449058	KIT00393R-1 COLECISTECTOMIA X1	21-345	211439702
6138165805	KIT00393R-1 COLECISTECTOMIA X1	21-345	211587723



6138570206	KIT00393R-1 COLECISTECTOMIA X1	21-345	211679150
6137728289	KIT00393R-1 COLECISTECTOMIA X1	21-345	211491631
6137386913	KIT00393R-1 COLECISTECTOMIA X1	21-345	211437936
2114945	KITW024	21-345	2114945
2116834	KITW024	21-345	2116834
2149074	KITG010V	21-345	2149074
2146703	KITH011A	21-345	2146703
6137276234	BOX KITSPIRENORWCHO SPIRE NORWICH LAP	21-345	211501572
6138563362	BOX KITSPIRENORWCHO SPIRE NORWICH LAP	21-345	211679252
6137276234	BOX KITSPIRENORWLAP SPIRENORWICHTAPP	21-345	211391138
6137959043	BOX KITSPIRENORWLAP SPIRENORWICHTAPP	21-345	211536486
6138831834	BOX KITSPIRENORWLAP SPIRENORWICHTAPP	21-345	211738982
6137276234	BOX KITSPIRENORWCHO SPIRE NORWICH LAP	21-345	211517514
6137276234	BOX KITSPIRENORWCHO SPIRE NORWICH LAP	21-345	211517190

**URGENT MEDICAL DEVICE Field Safety Corrective Action**

**Custom Procedure kits containing certain production lots of Clarify™ Visualization System**

**VERIFICATION FORM**  
**PLEASE COMPLETE THIS FORM IN ITS ENTIRETY**

*[Please insert date the form was sent]*

<b>Customer Contact Details</b>	<b>Medtronic Contact Details</b>
<b>Hospital Name:</b> <b>Covidien/Medtronic Account Number:</b>	<b>To:</b> <i>[please insert name]</i>
<b>Collection Address:</b> <b>Department:</b> Street: City: Postal Code: Contact Person at Point of Collection: Opening Hours:	<b>Address:</b> <i>[please insert Medtronic address]</i>
<b>Distributor Name - where your stock is being returned to (if applicable):</b>	<b>Telephone:</b> <i>[please insert Medtronic telephone number]</i>
<b>Telephone:</b>	<b>Fax:</b> <i>[please insert Medtronic fax number]</i>
<b>Fax:</b>	<b>E-mail:</b> <i>[please insert contact e-mail address]</i>
<b>E-mail:</b>	

**Item Codes: Refer to attachment A in the Urgent Field Safety Notice.**

Please list the quantity of affected product at your facility, if you have **no** inventory, please tick the box below.

**No Inventory (Please check):**

<b>Item/Kit Code</b>	<b>Invoice or Despatch Note (if available)</b>	<b>Lot number</b>	<b>Quantity (Eaches or Boxes) Please specify</b>


- **Please complete this form and return it to Medtronic even if you have no affected inventory**

Information for the courier:

Number of parcels to collect: \_\_\_\_\_

Weight:  < 45kg       > 45kg

**By signing this form I confirm that I have read and understand the Urgent Field Safety Notice from Medtronic regarding specific production lots of the Covidien Clarify™ visualization system issued dated October, 2016**

<b><u>Customer Name: (Please Print)</u></b>	<b><u>Signature:</u></b>	<b><u>Date:</u></b>

- Please fax or email this form back to Medtronic within 10 days using the contact details referenced at the top of this form.
- Customer Service will contact you directly to organise return of affected kits and credit will be given for returned products.
- Please don't send the goods back before having received the return documentation.
- **This action is being taken with the knowledge of the [add local Competent Authority].**