

Urgent Field Safety Notice

Model Number	Product Description
11001G	DLP® Extension Line Adapters 20 in length
13001	DLP® Antegrade/Retrograde Adapter
15004	DLP® Cardioplegia Adapter with Pressure Port
25009	DLP® Pressure Monitoring Extension Line Adapters
25010	DLP® Pressure Monitoring Extension Line Adapters
61000	DLP® Pressure Disposable Pressure Display Sets
62000	DLP® Pressure Disposable Pressure Display Sets

Recall of Specific of Specific Lot numbers (see Appendix A)

23 June 2017

Medtronic reference: FA778

Dear Healthcare Professional,

The purpose of this letter is to advise you that Medtronic is conducting a voluntary product recall for specific lots of the seven (7) Medtronic DLP product codes listed above, and shown pictorially below. See Appendix A for the complete list of affected lot numbers.

Issue Description:

During the manufacturing process, Medtronic identified small pinholes, approximately 1 mm or less in diameter, in a single packaging configuration of sterile pouches. Based on internal investigation, all products in this packaging configuration manufactured since March 1, 2016 are potentially affected. The result is a potential sterile barrier breach. No other lots of these Medtronic product codes or other product codes are affected.

As of June 12, 2017, there have been zero (0) complaints received for the affected lots reporting damage or a sterile barrier breach in the packaging, or any adverse patient effects or harms.

Potential patient harm is infection, which can also result in secondary harms if a sterile barrier breach in the packaging is present, but not detected prior to use.

For patients who were treated using one of the potentially affected products, there are no recommendations for special follow-up, physician communication, or a change in patient management beyond routine practice.



Customer Actions:

Our records indicate that one or more affected products were distributed to your facility. As a result, Medtronic requests that you take the following actions:

1. Immediately identify and quarantine all unused, affected product in your inventory.
2. Return all unused, affected product in your inventory to Medtronic. Your Medtronic Representative will assist you in the return and replacement of this product as necessary.

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected products have been transferred.

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

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. Please contact your Medtronic Representative directly or via telephone number +353 1 5111400 with any questions related to this Urgent Field Safety Notice.

Sincerely,

David Dunham
Regulatory Affairs & Quality Manager - UK & Ireland

Appendix A: List of Affected Lot Numbers

Model Number	Product UPN/GTIN	Lot Number	Model Number	Product UPN/GTIN	Lot Number	Model Number	Product UPN/GTIN	Lot Number
11001G	20613994918554	2016020769	25009	20613994918608	2016091068	61000	20613994846604	2016091410
11001G	20613994918554	2016030796	25009	20613994918608	2016100893	61000	20613994846604	2016100571
11001G	20613994918554	2016040778	25009	20613994918608	2016110439	61000	20613994846604	2016100572
11001G	20613994918554	2016060872	25009	20613994918608	2016120464	61000	20613994846604	2016100875
11001G	20613994918554	2016061425	25009	20613994918608	2017010278	61000	20613994846604	2016100876
11001G	20613994918554	2016070500	25009	20613994918608	2017030102	61000	20613994846604	2016110851
11001G	20613994918554	2016081190	25009	20613994918608	2017030576	61000	20613994846604	2016110852
11001G	20613994918554	2016090516	25009	20613994918608	2017031125	61000	20613994846604	2016111130
11001G	20613994918554	2016091016	25010	20613994918585	2016020841	61000	20613994846604	2016111131
11001G	20613994918554	2016110504	25010	20613994918585	2016031522	61000	20613994846604	2016111132
11001G	20613994918554	2016120414	25010	20613994918585	2016050255	61000	20613994846604	2016111133
11001G	20613994918554	2017010236	25010	20613994918585	2016070494	61000	20613994846604	2016120836
11001G	20613994918554	2017011281	25010	20613994918585	2016081243	61000	20613994846604	201612C037
11001G	20613994918554	2017030506	25010	20613994918585	2016090923	61000	20613994846604	2017010052
13001	20613994677611	2016020795	25010	20613994918585	2016110054	61000	20613994846604	2017020120
13001	20613994677611	2016030222	25010	20613994918585	2016110837	61000	20613994846604	2017020122
13001	20613994677611	2016030813	25010	20613994918585	2017040714	61000	20613994846604	2017021065
13001	20613994677611	2016031019	61000	20613994846604	2016020865	61000	20613994846604	2017021066
13001	20613994677611	2016040411	61000	20613994846604	2016030859	61000	20613994846604	2017030114
13001	20613994677611	2016040614	61000	20613994846604	2016031538	61000	20613994846604	2017030115
13001	20613994677611	201604C004	61000	20613994846604	2016040539	61000	20613994846604	2017030116
13001	20613994677611	2016050516	61000	20613994846604	2016040859	61000	20613994846604	2017030117
13001	20613994677611	2016050769	61000	20613994846604	2016050268	61000	20613994846604	2017030118
13001	20613994677611	2016051176	61000	20613994846604	2016050556	61000	20613994846604	2017030119
13001	20613994677611	2016060227	61000	20613994846604	2016051179	61000	20613994846604	2017030595
13001	20613994677611	2016061042	61000	20613994846604	201605C063	61000	20613994846604	2017030951
13001	20613994677611	2016061440	61000	20613994846604	201605C064	61000	20613994846604	2017031135
13001	20613994677611	2016070193	61000	20613994846604	201605C065	61000	20613994846604	201703C055
13001	20613994677611	2016070921	61000	20613994846604	201605C066	62000	20613994846642	2016040236
13001	20613994677611	2016070922	61000	20613994846604	201605C067	62000	20613994846642	2016040540
13001	20613994677611	2016080373	61000	20613994846604	201605C068	62000	20613994846642	2016041196
13001	20613994677611	2016090545	61000	20613994846604	201605C069	62000	20613994846642	2016051245
13001	20613994677611	2016091365	61000	20613994846604	2016060275	62000	20613994846642	201605C015
13001	20613994677611	2016100614	61000	20613994846604	2016060525	62000	20613994846642	201605C016
13001	20613994677611	2016101189	61000	20613994846604	2016060896	62000	20613994846642	2016060226
13001	20613994677611	2016101190	61000	20613994846604	2016060897	62000	20613994846642	2016060526
13001	20613994677611	2016110125	61000	20613994846604	2016061082	62000	20613994846642	2016060899
13001	20613994677611	2016110825	61000	20613994846604	2016061083	62000	20613994846642	2016061085
13001	20613994677611	2016111024	61000	20613994846604	2016061084	62000	20613994846642	2016061086
13001	20613994677611	2016111026	61000	20613994846604	2016061476	62000	20613994846642	2016061482
13001	20613994677611	201612C046	61000	20613994846604	2016061477	62000	20613994846642	2016070542
13001	20613994677611	2017010914	61000	20613994846604	2016061478	62000	20613994846642	2016070964
13001	20613994677611	2017010915	61000	20613994846604	2016061479	62000	20613994846642	2016070965
13001	20613994677611	2017020855	61000	20613994846604	2016061480	62000	20613994846642	2016080350
13001	20613994677611	2017020856	61000	20613994846604	2016070727	62000	20613994846642	2016081588
13001	20613994677611	2017021022	61000	20613994846604	2016070744	62000	20613994846642	2016081589
13001	20613994677611	201702C012	61000	20613994846604	2016070753	62000	20613994846642	2016091146
13001	20613994677611	2017030536	61000	20613994846604	2016070962	62000	20613994846642	2016100654

13001	20613994677611	2017031116	61000	20613994846604	2016070963	62000	20613994846642	2016110453
13001	20613994677611	2017040101	61000	20613994846604	201607C046	62000	20613994846642	2016110854
15004	20613994900412	2016031072	61000	20613994846604	201607C047	62000	20613994846642	2016120837
15004	20613994900412	2016031509	61000	20613994846604	2016080349	62000	20613994846642	2017010583
15004	20613994900412	2016050243	61000	20613994846604	2016081585	62000	20613994846642	2017010945
15004	20613994900412	2016081219	61000	20613994846604	2016081586	62000	20613994846642	201701C037
15004	20613994900412	2016100630	61000	20613994846604	2016081587	62000	20613994846642	2017021067
15004	20613994900412	2016120083	61000	20613994846604	2016090237	62000	20613994846642	2017021068
15004	20613994900412	2016120448	61000	20613994846604	2016090593	62000	20613994846642	2017030596
15004	20613994900412	2017040113	61000	20613994846604	2016090594	62000	20613994846642	201703C104
25009	20613994918608	2016090217	61000	20613994846604	2016091409	62000	20613994846642	2017040147