Medtronic

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# URGENT FIELD SAFETY NOTICE

## Covidien Custom Procedure Kits containing certain production lots of Endo GIA™ Ultra Universal Stapler Handles

December 04, 2015

**Attention: Risk Management Director and O.R. 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 item codes and production lots of Covidien Endo GIA™ Ultra Universal Stapler Handles which are included in Covidien Custom Procedure Kits that have been shipped to your facility. This Field Safety Corrective Action (FSCA) is being conducted following customer reports of instruments failing to fire or partially firing and reports of the instrument articulating lever disengaging during use. If the instrument fails to fire or partially fires, or if the articulating lever disengages, the surgeon may be required to replace the device to continue the procedure. No patient injuries have been reported related to these issues. The complaint rate for the instrument fails to fire or partially fires for the affected lots is 0.04% and the complaint rate for the articulating lever disengaging is .006%.

Medtronic is requesting that you quarantine any remaining inventory of the Covidien Custom Procedure Kits detailed below. Affected product that is unused should be returned as described in the Required Actions section below. If you have distributed Endo GIA™ Ultra Universal Stapler Handles to other persons or facilities, please promptly forward the information from this letter to those recipients. All affected units must be returned.

| Kit Parent Code | Order Number |
|---|---|
| (K) GASTRIC BYPASS V3 KIT | 0070546 |
| (K) GASTRIC BYPASS V3 KIT | 0077567 |
| (K) GASTRIC BYPASS V3 KIT | 0078039 |
| (K) GASTRIC BYPASS V3 KIT | 0078331 |
| (K) GASTRIC BYPASS V3 KIT | 0078796 |
| (K) GASTRIC BYPASS V3 KIT | 0082741 |
| (K) GASTRIC BYPASS V3 KIT | 0084954 |
| (K) GASTRIC BYPASS V3 KIT | 0090151 |
| (K) GASTRIC BYPASS V3 KIT | 0090180 |
| (K) GASTRIC BYPASS V3 KIT | 0090620 |

**Required Actions:**

1. Please quarantine and discontinue use of the affected Covidien Custom Procedure Kit codes listed above.

2. A Medtronic Sales Representative will arrange to visit your facility in order to inspect the affected inventory of the Endo GIA™ Ultra Universal Stapler Handles and arrange for it to be returned to Medtronic.

3. The Sales Representative will assist you with the completion of the attached Returns Verification form, which should be completed in full & provided to the Sales Representative. Your Medtronic Sales Representative will provide you with replacement Endo GIA™ Ultra Universal Stapler Handles to complete the affected kits.

This action is being taken with the knowledge of the Irish Competent Authority, The Health Products Regulatory Authority (HPRA).

If you are aware of any incidents related to this issue, please contact your local Medtronic Representative using the contact information stated above to provide information regarding those events so regulatory reporting obligations can be fulfilled.

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic Product Specialist Naomi Clear by telephone 087 9330667 or by e-mail at naomi.clear@medtronic.com.

Sincerely,

Audrey Doyle

Audrey Doyle
RA Specialist, Email: audrey.doyle@medtronic.com Tel: 01 4381609