

Urgent Field Safety Notice **Covidien Signia™ small diameter curved tip intelligent reload** **Recall**

March 2021

Medtronic reference: FA965

Dear Customer / Risk Manager,

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific production lots of its **Covidien Signia™ small diameter curved tip intelligent reload**.

Issue Description:

This voluntary recall is being conducted due to the potential for the device safety interlock to fail. The safety interlock prevents an empty single-use reload from being erroneously fired a second time. If the safety interlock fails and the empty single-use reload is fired a second time, the stapler may cut tissue but no staples will deploy from the empty reload, potentially resulting in a failed anastomosis, bleeding, tissue trauma, and the potential need to convert to an open procedure.

There is no possibility for harm if the device is fired once in accordance with the instructions for use or if a second firing is attempted using a Signia™ power handle; the power handle has software that prevents a second firing. The potential for the safety interlock failure exists only when an affected Signia™ small diameter curved tip intelligent reload is erroneously fired a second time on a manual stapler. This issue was identified during in-process Quality testing at the manufacturing facility. Manufacturing process improvements have been instituted to address the component defect which can result in the safety interlock failing. There have been no reports from customers related to this issue.

This voluntary recall affects only the item codes with associated lot numbers listed on Attachment A.

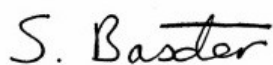
Required Actions:

1. Please immediately quarantine and discontinue use of affected item codes with associated lot numbers listed on Attachment A.
2. Please return affected product as indicated below. All unused products from the affected item codes and associated lot numbers must be returned. Your local Medtronic Field Representative can assist you as necessary in initiating the return of this product.

Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic representative at 01 511 1400.

Sincerely,



Samantha Baxter
Regulatory Affairs Manager
UK and Ireland

Attachment A

Item Code	Material/Part Description:	Affected Lot Numbers			
SIGSDL45CTVT	Covidien Signia™ Small Diameter Curved Tip Intelligent Reload 45 mm Vascular/Thin - 8 mm Long	N0A1038UY	N0E0016UY	N0F0616UY	N0K0934UY
		N0B0493UY	N0F0254UY	N0F0817UY	N0M0334UY
		N0C0436UY	N0F0518UY	N0G0388UY	N9K1095UY
		N0D0731UY	N0F0615UY	N0J0859UY	N9L0797UY
SIGSDS30CTV	Covidien Signia™ Grey Small Diameter Curved Tip Intelligent Reload 30 mm Vascular 8 mm - Short	N0A0191UY	N0D0392UY	N0F0406UY	N0L0708UY
		N0B0657UY	N0E0133UY	N0G0907UY	N9K0376UY
		N0C0349UY	N0E0956UY	N0J0746UY	N9K1093UY
		N0C0492UY	N0E1026UY	N0K0248UY	N9L0796UY
		N0C1008UY	N0F0202UY	N0K0803UY	N9M0418UY
		N0D0283UY	N0F0221UY	N0L0307UY	N9M0651UY
SIGSDS30CTVT	Covidien Signia™ Small Diameter Curved Tip Intelligent Reload 30 mm Vascular/Thin 8 mm - Short	N0A0274UY	N0D0037UY	N0G0491UY	N0K1016UY
		N0A0897UY	N0D0391UY	N0G0736UY	N0L0077UY
		N0B0640UY	N0E0175UY	N0J0510UY	N0M0063UY
		N0B0937UY	N0E0802UY	N0J0680UY	N0M0259UY
		N0C0144UY	N0F1055UY	N0J0999UY	N9K1094UY
		N0C0486UY	N0G0185UY	N0K0584UY	N9L0795UY
		N0C1115UY	N0G0250UY	N0K0805UY	

Identifying Affected Product

