Medtronic
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URGENT: MEDICAL DEVICE RECALL

Covidien Signia™ Small Diameter Curved Tip Intelligent Reload

Model No. SIGSDL45CTVT

24 September 2025 | 23:41 PDT

Attention: Risk Management Director and O.R Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

Dear Risk Manager/Distributor/Healthcare Professional,

The purpose of this letter is to advise that Medtronic is initiating a voluntary medical device recall for specific lot numbers of the Covidien Signia™ Small Diameter Curved Tip Intelligent Reload ("reload") Model No. SIGSDL45CTVT listed below.

Issue Description:

During testing, Medtronic identified that under certain firing conditions, reloads were found to articulate in an uncontrolled manner potentially causing disruption to the staple line and harm to tissue. The issue is related to components in impacted reloads that are not fully secure, which leads to uncontrolled articulation of the jaws (Refer to image 1 below). The issue can occur using either the Endo GIA™ Ultra Universal Stapler or Signia™ Stapling System. While using Endo GIA™ Ultra Universal Stapler or Signia™ Stapling System, uncontrolled articulation of the jaws in the left or right direction can occur while firing the reload. Uncontrolled articulation is also possible if the reload is being used outside of the indicated tissue thickness range.

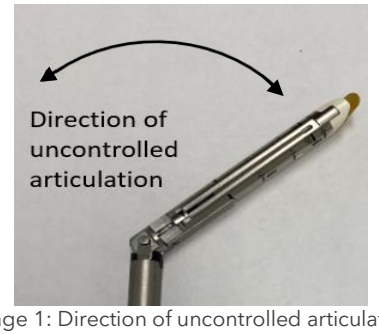


Image 1: Direction of uncontrolled articulation

Risk to Health:

If uncontrolled articulation occurs, it can lead to a potential patient harm of hemorrhage, especially in the vascular application, that could result in death, tissue damage/perforation, infection, hemo/pneumothorax, and delay of surgery. Reloads are indicated for the pediatric population, and potential harms for that population are the same as other indicated populations.

As of 22-SEPT-2025, Medtronic has not received any complaints related to this action and there's been no reports of patient harm in relation to this action.

Patient Management:

There are no actions required for patients where the affected devices have already been used during a procedure. These patients should continue to be monitored as usual in accordance with standard care protocols.

Product Scope:

Product Name	Model Number	GTIN/Unique Device Identifier	Lot Number
Medtronic Signia™ Small Diameter Curved Tip Intelligent Reload	SIGSDL45CTVT	20884521741840 10884521741843	N5F1971Y N5F1723Y N5D1858UY N5B1134UY

Customer Actions:

Our records show that your facility has received impacted product. Medtronic requests you take the following actions:

- Identify and quarantine all unused impacted product listed above.
- See Attachment A for guidance on identifying affected lots.
- Return all quarantined devices to Medtronic. Your Medtronic sales representative can assist you in the return of the affected product as necessary.
    - If purchased from a distributor, contact your distributor directly to arrange for the return of the devices back to your distributor.
- Please complete and return the enclosed Customer Confirmation Form to your local Medtronic representative even if you **do not** have unused inventory.
- Pass on this notice to all those who need to be aware within your organization or to any organization where the listed affected lots may have been transferred or distributed.

Additional Information:

Medtronic is communicating this information to the appropriate regulatory agency in your country.
Adverse events or quality problems experienced with this product should be reported to your local Medtronic representative.

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 Field Representative.

Sincerely,

Signed by:
Siak Wah Yew
Signer Name: Siak Wah Yew
Signing Reason: I approve this document
Signing Time: 24 September 2025 | 23:40 PDT
99B5834721984194B5948835E56FD5D9

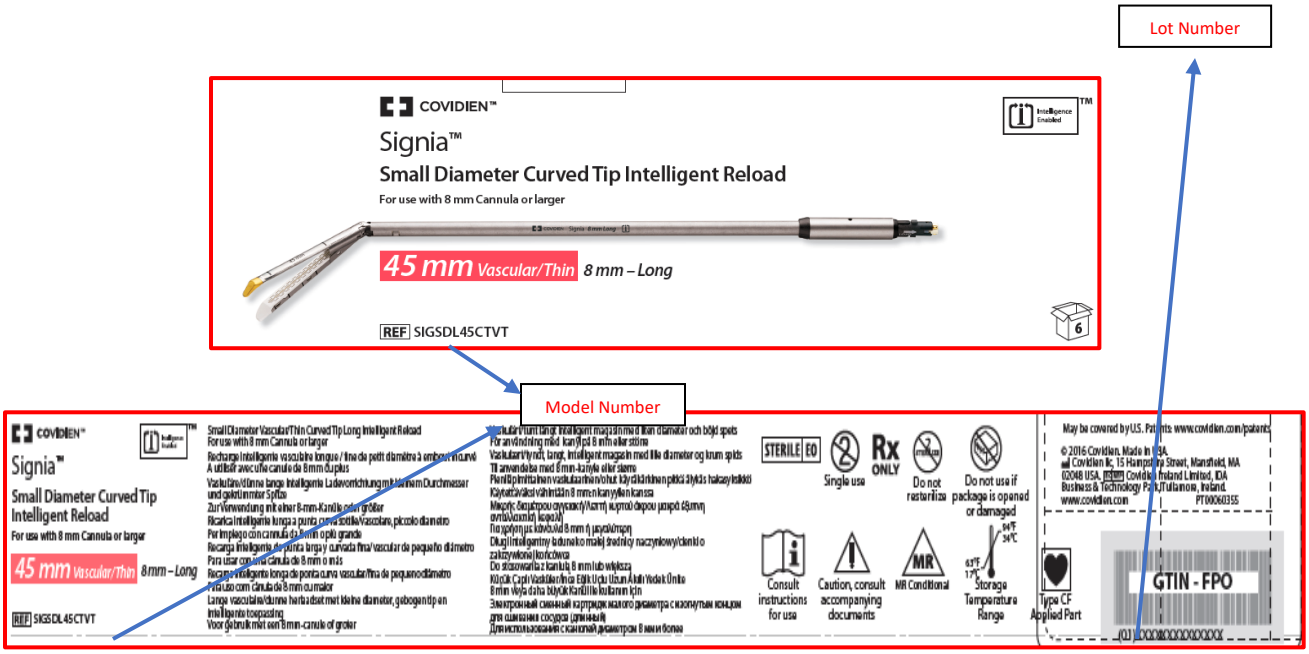
Quality and Regulatory Affairs Lead
Malaysia

Enclosures:
Attachment A: Identifying affected lots
Customer Confirmation Form

Attachment A:

IDENTIFYING AFFECTED LOTS

Locate product information on product labels in your inventory



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Customer Confirmation Form

URGENT: MEDICAL DEVICE RECALL

Covidien Signia™ Small Diameter Curved Tip Intelligent Reload

Model No. SIGSDL45CTVT

For completion by Medtronic Customers Only – Please complete all fields below and return all pages as soon as possible even if you do not have any product to return.

Customer Contact Details		Medtronic Contact Details
Distributor/Hospital/Clinic/Patient name:		**Name:**
		Contact:
Address:		**Email:**
Phone no:	**Email:**	

If you have no affected stock to be returned, please tick the appropriate box, and sign off the form.

Do you have affected stock for return? (Please tick only ONE):

☐ **NONE**. I have examined our inventory for products covered by this notification and confirm that we have none to return. All affected units were previously consumed.

☐ **YES**, I have examined our inventory and confirm to still have the affected products that remain unconsumed. WE WILL RETURN the units listed in the following table.

☐ We **REFUSE** to return the units in our inventory. We understand the risks and take full responsibility for the continued use.

CFN/ Product Number	Lot/Serial Number	Quantity (in units)

By signing this form, I confirm that I have read the Urgent Medical Device Recall Notification Letter, dated 24 September 2025 | 23:44 PDT **from Medtronic regarding the Covidien Signia™ Small Diameter Curved Tip Intelligent Reload Model No. SIGSDL45CTVT and taken appropriate action.**

Please complete all fields and sign the form as indicated below and return the completed form to your local Medtronic representative.

Name (print): _____ Signature: _____ Stamp: _____ Date: dd Mmm yyyy

Return Instructions:

- Identify and quarantine all unused affected products listed in Attachment A.
- Return all quarantined devices to Medtronic. Your Medtronic sales representative can assist you in the return of the affected product as necessary.
- If purchased from a distributor, contact your distributor directly to arrange for the return of the product back to your distributor.

Note: The addressee may continue to receive reminders of this notice until a response is received.

For questions, contact your local Medtronic Representative.