Medtronic
Medtronic Malaysia Sdn Bhd
(Formerly known as Covidien Sendirian Berhad)
Reg.No.: 200301009341 (611761-M)
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No.1, Jalan SS7/26A, Kelana Jaya
47301 Petaling Jaya
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www.medtronic.com

Urgent: Medical Device Recall

DLP™ Vessel Cannulae Incorrect Labeling

Product Description	Model #	Lot #
DLP™ Vessel Cannulae	30000	2023020890
		202305C126
		2023020889

08 February 2024 | 05:22 PST

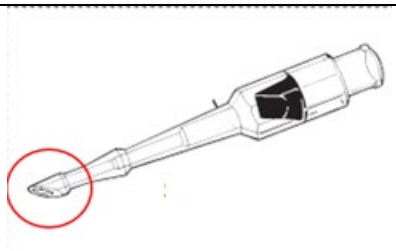
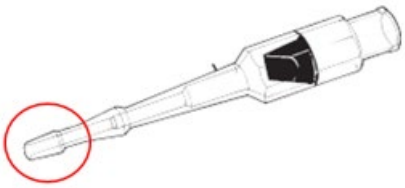
Attention: Risk Management Director and O.R Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

Dear HealthCare Professional/Risk Manager,

Medtronic is writing to inform you of incorrect labeling for three manufactured lots of the DLP™ Vessel Cannulae for the model and lot numbers listed above. Medtronic records indicate you have received at least one of the listed products. No other product model or lot numbers are affected by this issue.

Issue Description:
During manufacturing of the three listed lot numbers, product for model 30001 was incorrectly labeled as model 30000. See figure 1 below for correct product model descriptions.

Figure 1: Differences in DLP™ Vessel Cannulae models 30000 and 30001

Model #	Image of Product	Difference
30000		Beveled Tip
30001		Blunt Tip

As of January 3, 2024, Medtronic has received four (4) customer reports for this issue. There have been no reported adverse patient consequences associated with this issue. Both devices have the same function, and the tip type is personal preference by the user. The potential harm when the mislabeling is identified prior to use is procedure delay while a preferred cannulae is located. If the mislabeling is not identified prior to use, and the clinician uses the mislabeled cannulae, the potential harm is prolonged procedure (continual use).

Patient Recommendations:

Patients previously supported with an impacted device face no additional risk from the issue described in this communication and should continue to be monitored by your practice's normal follow-up procedures.

Customer Actions:

Medtronic requests that you take the following actions:

- Review your inventory for listed product.
- Immediately identify and quarantine all unused, listed product in your inventory.
- Complete the enclosed Customer Confirmation Form and hand back or scan then email to your local Medtronic field representative. This form must be returned even if you do not have any affected product in your possession.
- Return all unused product from the affected lot in your inventory to Medtronic. Please contact your local Medtronic field representative to initiate a return. Your Medtronic sales representative can assist you in the return of affected product as necessary.

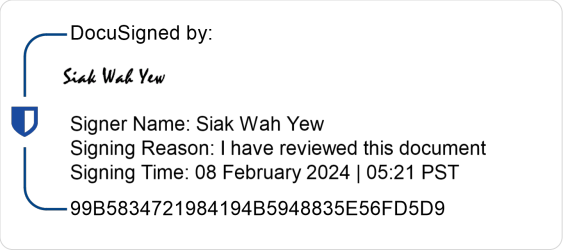
- If purchased from a distributor, contact your distributor directly to arrange for the return of the product back to your distributor.
- Please share this notification with others in your organization as appropriate. If product listed above has been forwarded to another facility, please notify the facility of this Medtronic Urgent Medical Device Recall.
- Please maintain a copy of this communication in your records.

Additional Information:

Medtronic is notifying the applicable regulatory authority of this issue.

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 local Medtronic field representative.

Sincerely,



Quality and Regulatory Affairs Lead
Malaysia

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Customer Confirmation Form

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For completion by Medtronic Customers Only – Please complete all fields below and return all pages immediately.

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 remaining inventory of the affected units? (Please select only ONE):

☐ no, **NONE** of the affected inventory to be returned. I have examined our inventory for product/s covered by this and confirm that all affected was/were previously consumed.

☐ **YES**, affected inventory to be returned. I have examined our inventory and have the affected product/s listed in the following table that remain/s unconsumed and is to be returned.

Model Number	Lot Number	Quantity to be returned (in units)
30000	2023020890	

By signing this form I confirm that I have read the Urgent Medical Device Recall Notification Letter, dated

08 February 2024 | 05:22 PST **from Medtronic regarding DLP™ Vessel Cannulae and taken appropriate action.**

Please complete and sign the form as indicated below and hand or scan then email back to your local Medtronic representative.

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

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