Medtronic (Schweiz) AG
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Urgent Field Safety Notice

DLP™ Single Stage Venous Cannulae Incorrect Labeling

Recall

Product Description	Model Number	Lot Number
DLP™ Single Stage Venous Cannulae with right angle metal tip	67312	2023090954
		202312C065

July 2024

Medtronic Reference: FA1396

EU Manufacturer Single Registration Number (SRN): US-MF-000019977

Dear HealthCare Professional/Risk Manager,

Medtronic is writing to inform you of an incorrect component for two manufactured lots of the DLP™ Single Stage Venous 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 two listed lot numbers, cannula for model 66118 (DLP™ Single Stage Venous Cannulae – straight tip) was incorrectly placed into a product labeled as model 67312 (DLP™ Single Stage Venous Cannulae – right angle metal tip). See figure 1 below for correct product model descriptions.

Figure 1: Differences in DLP™ Single Stage Venous Cannulae models 67312 and 66118

Model Number	Image of Product	Difference
67312		Right angle metal tip
66118		Straight tip

Until May 22, 2024, Medtronic has received one (1) customer report 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.
- Return unused, listed product in your inventory to Medtronic. Your local Medtronic Representative can assist you with the initiation of the return.
- Please complete and return the enclosed Customer Acknowledgment Form even if you do not have any affected product in your possession.
- 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 Urgent Field Safety Notice.
- Please maintain a copy of this communication in your records.

Additional Information:

Medtronic has notified the Competent Authority of your country 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 Medtronic Field Representative.

Sincerely,

Medtronic (Schweiz) AG

Enclosures:

- Customer Acknowledgement Form