Medtronic Limited
Building 9
Croxley Park
Hatters Lane
Watford, Herts
WD18 8WW

Tel: 01923 212213

Fax: 01923 241004
www.medtronic.co.uk

Urgent Field Safety Notice

DLP™ Vessel Cannulae Incorrect Labeling

Recall

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

February 2024

Medtronic Reference: FA1396

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

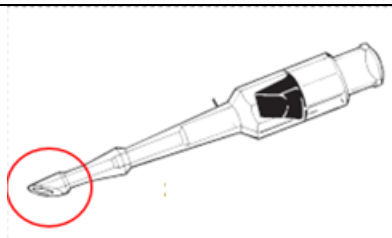
Dear HealthCare Professional/Risk Manager,

Medtronic is writing to inform you of 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

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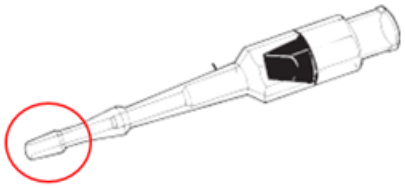
30001		Blunt Tip

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.
- Return all unused affected product in your inventory to Medtronic. Your local Medtronic Representative can assist you with the initiation of the return.
- Please share this notice with all those who need to be aware of this issue within your organization or to any organization where the potentially affected devices have been transferred and maintain a copy of this notice in your records.
- Please complete and return the enclosed Customer Acknowledgment Form even if you do not have unused inventory.

Additional Information:

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

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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 or via email: rs.regulatoryuk-ire@medtronic.com.

Sincerely,

H.Hussain

Heidar Hussain
Associate Regulatory Affairs Specialist

Enclosures:

- Customer Acknowledgement Form