Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 106 **dated** 28/7/2024 **Regarding NCMDR Recall of DLP™ Single Stage Venous Cannulae with right angle metal tip from (mfr: Medtronic Inc).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

Circular No. 106 / 2024

22-01-1446 H
28-07-2024

Recall of DLP™ Single Stage Venous Cannulae with right angle metal tip from Medtronic Inc.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21126
Product	DLP™ Single Stage Venous Cannulae with right angle metal tip.
Description	Cannula.
Manufacturer	Medtronic Inc.
Local agent	AL Zahrawi Medical Supplies.
The affected products	Model Number: 67312 Lot Number: 2023090954
Reason	An incorrect component for the above product. Cannula for model 66118 (DLP™ Single Stage Venous Cannulae – straight tip) was incorrectly placed into it.
Action	1. Please immediately identify, quarantine all unused affected product in your inventory and return them to Medtronic. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

سلطنة عمان - وزارة الصحة - مركز سلامة الدواء
SULTANATE OF OMAN - MINISTRY OF HEALTH
SAFETY CENTER

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
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Medtronic

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

July 2024

Medtronic Reference: FA1396

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,

Hussein Khaldieh
OU Manger - Cardiac Surgery

Enclosures:

- Customer Acknowledgement Form

Medtronic

CUSTOMER ACKNOWLEDGEMENT FORM

Please email or fax this form back to Medtronic (even if you do not have affected inventory):

nahar.s.alsurayi@medtronic.com

Urgent Field Safety Notice - Recall

FA1396 July 2024: DLP™ Single Stage Venous Cannulae – Incorrect Labeling

Customer Contact Details		
Company name:		Account number (optional):
Address:	City:	Country:

- I confirm that I have read and understood the Urgent Field Safety Notice
- I agree to pass on the Urgent Field Safety Notice to all those who need to be aware within our organization or to any organization where the potentially affected products have been transferred.
- I have reviewed our inventory, identified, and quarantined all unused affected products in our inventory, and I declare the following:

☐ No affected products are located at our facility.

☐ Affected products are located at our facility. See below table for details of affected products to be returned to Medtronic.

Name (print):	**Job title**: **Contact Number :**	**Date**:	**Signature**:

Please fill-in the section below only if you have affected stock:

Return Details			
Invoice or Delivery Note *(if available)*	**Item Code**	**Lot # / Serial #**	**Quantity** *(please count units inside of the box)*
☐ If you have more products to return, tick the box. Please create and send separate attachment with same data.			**Total**:

Contact Person at Point of Collection:		
Pick-up address / Department *(please provide location details. E.g.: collection/accessible area)*:		
City:		Post code:
Pick-up phone number:	Pick-up email:	
When the product will be ready for pick-up? *(Please allow 2 days for handling your request)*:		
Opening hours of the pick-up location:		Dimension LxWxH (in cm): … x … x …
# Pallets:	# Parcels:	Number of parcels weighing over 45 kg:

- Customer Service will contact you directly to organise return of affected products and credit will be given for returned products.
- Please don't send the goods back before having received the return documentation.
- Please package goods according to packaging instructions that will be provided upon confirmation & remove all labels from the inbound shipment.

Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Medical Devices Sector

قطاع الأجهزة الطبية

NCMDR

National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Recall

Reference Number: mdprc 019 07 24 000

Date submitted: 7/14/2024

Back

Manufacturer:	Medtronic Inc.
Device Type:	DLP™ Single Stage Venous Cannulae with right angle metal tip
Description:	Cannula
Medical Device Identifier:	Model Number: 67312 Lot Number: 2023090954
Reason of Field Safety Corrective Action:	An incorrect component for the above product. Cannula for model 66118 (DLP™ Single Stage Venous Cannulae – straight tip) was incorrectly placed into it.
Remedy Action:	Please immediately identify, quarantine all unused affected product in your inventory and return them to Medtronic.
Athorized Representative/Importer/Distributor:	Medtronic Saudi Arabia
Report Source:	NCMDR
Source Ref. Number:	SA-10-07-24-505
SFDA Comments:	SFDA urges all healthcare providers that have devices subjected to this safety alert to contact the company.
Attachments:	medtronic.pdf

View History