



HOSPITECH MANUFACTURING SERVICES SDN. BHD. 199601034155 (406507-H)

Sub Lot 1, Lot 6536, Batu 6, Jalan Bukit Kemuning, 40460 Shah Alam, Selangor Darul Ehsan, Malaysia

Tel: 03-51225199 (Hunting) Fax: 03-51225204

E-mail: hosmfg@hospitech.net Website: <http://hospitech.net/>

URGENT – RECALL

Suction Tube

Date: 6th September 2024

Dear Valued Customer,

Hospitech Manufacturing Services Sdn. Bhd. has initiated a voluntary medical device recall of specific lots of Suction Tube distributed in Malaysia.

Affected Products

The scope of this medical device recall includes the products listed below:

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THE FOLLOWING PRODUCT LOTS

PRODUCT NAME	PRODUCT CODE	PRODUCT LOTS
Suction Tube	SHM-STD-3M	STD 240330 AX
Suction Tube	SHM-STD-3M	STD 240238 AX
Suction Tube	SHM-STD-3M	STD 240538 AX
Suction Tube	SHM-STD-360	STD 240437 AX

Reason for the Voluntary Recall

Hospitech Manufacturing Services Sdn. Bhd. has identified a manufacturing issue on a specific extrusion machine mould that resulted in a smaller internal diameter of Suction Tube. A smaller internal diameter may cause difficulty for user during procedures. The occurrence of this defect is rare.

Hospitech Manufacturing Services Sdn. Bhd. has identified and corrected the root cause of the manufacturing issue that led to this recall.

Action Required

1. Determine whether you have inventory of the lots listed as above.
2. Quarantine all product(s) in scope and return all inventory for product replacement.
3. Complete the Customer Acknowledgement Letter (Attachment 1) and return the affected product. Please return the Customer Acknowledgement Letter even if you do not have product subject to this recall.
4. If any of the affected product(s) have been forwarded to another facility, contact that facility to arrange for return and provide them with the Customer Acknowledgement Letter.
5. Please share this information with all the appropriate staff at your facility.
6. Please keep a copy of this notice for your awareness and records.



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At Hospitech Manufacturing Services Sdn. Bhd., our first priority is to our customers and their patients, and that includes the safe and effective use of our products. We recognize the recall of this product may be disruptive to your facility and we appreciate your assistance in this matter.

Best Regards,

A handwritten signature in blue ink, appearing to read 'Krystine Rode''.

Krystine Rode'
QA/RA Manager

Attachment 1: Customer Acknowledgement Form



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Attachment 1: Customer Acknowledgement Letter

Customer Acknowledgement Letter

Please complete the following information: Please check the checkbox

- We hereby acknowledge receipt of this medical device recall letter from Hospitech Manufacturing Services Sdn. Bhd. regarding Suction Tube. We will distribute this information to all staff within our facility that use the impacted products and will maintain a copy of this notice with the identified product(s).

Product Receipts – please check one:

- We have NO inventory of product subject to this recall.
- We have product subject to this recall. We will quarantine all impacted lots and return for product exchange.

If you have product subject to this recall to return, please make a photocopy of your completed Customer Acknowledgement Letter and enclose with your return. Thank you for your cooperation.

PRODUCT NAME	PRODUCT CODE	PRODUCT LOTS	QUANTITY RETURNING (PCS)
Suction Tube	SHM-STD-3M	STD 240330 AX	
Suction Tube	SHM-STD-3M	STD 240238 AX	
Suction Tube	SHM-STD-3M	STD 240538 AX	
Suction Tube	SHM-STD-360	STD 240437 AX	

Hospital / Company Name	
Name / Title	
Phone Number	
Signature & Date	
Hospital / Company Stamp	

Note: If the verification section is answered on behalf of more than one facility and/or individual, please clearly indicate the name and address of the facility and/or individual on this page of the notification.

Please complete and email to krystine@hospitech.net