smiths medical
bringing technology to life

6000 Nathan Lane N.
Minneapolis, MN 55442
https://www.smiths-medical.com

URGENT: FIELD SAFETY NOTICE

Medex ™ Infusion Extension Set, Model MX618CZ

10th July 2023

Dear Valued Customers:

Smiths Medical is issuing this Urgent Field Safety Notice to notify you of a potential defect with the Medex™ Extension Sets. This letter details the issue and the required steps for you to perform.

Issue:
Smiths Medical has identified the potential for a manufacturing defect with a specific lot of the Medex™ Infusion Extension Set (Model number MX618CZ, Lot number 4306091) which may result in an occlusion occurring in the Extension Set that can prevent fluid administration.

The occlusion was attributed to the excessive adhesive applied in the bonded area between the tubing and the adapter, resulting in a blockage. Refer to Figure 1.

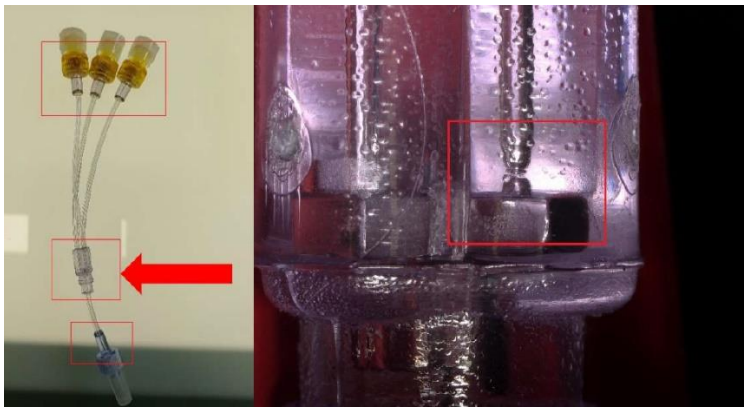

Figure 1 – Medex ™Extension Set with Blockage

Potential Risk:
If an occlusion occurs in the Extension Set, this will prevent the administration of medications. This can lead to an interruption or a delay of therapy, until the occluded Extension Set is replaced. If a life sustaining drug is to be delivered to a patient, the inte rruption or delay of therapy may lead to patient harm. To date, Smiths Medical has not received reports of serious injuries or deaths associated with this issue.

Affected Product:
Our records indicate that you may have received some of the affected products, which were distributed between 15 September 2022 and 14 October 2022 time frame. The affected item and lot number is provided in Table 1, below:

Table 1: Affected Product and Lot Numbers

List Number	Product Description	Lot Number
MX618CZ	Medex ™Infusion Extension Set	4306091

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Required Actions for Users:

1) Please discontinue the use and distribution of the affected product immediately. Check your inventory and quarantine all affected product at your facility.

2) Inform potential users of the product in your organization of this notification and complete the attached response form indicating whether you intend to return this product to Smiths Medical or destroy it locally. Return the completed response form to EMEA-Quality@icumed.com , even if you do not have the affected product.

3) If you have distributed the product further, immediately notify your accounts that received the product identified in the Affected Product / Table 1 sections of this notification and ask your customers to complete a response form and return to you for overall completion.

4) Please contact Customer Service using the information provided below for assistance reordering replacement product.

Follow up Actions by Smiths Medical:
Upon receipt of the affected product, or upon receipt of a Certificate of Destruction, Smiths Medical will credit you for any product returned/destroyed. You will only receive credit for product that you return or that you certify has been destroyed locally. NOTE: Credits for product purchased through a distributor will be credited by the distributor.

For further inquiries, please contact Smiths Medical using the information provided below.

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	globalcomplaints@icumed.com	To report adverse events or product complaints
Customer Support	Tel: +49 (0)89 242959 - 0 Fax: +49 (0)89 242959 – 310 Email: bestellung@icumed.com	Additional information or assistance

Smiths Medical is committed to patient safety and is focused on providing exceptional product reliability and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,

Joe Canavan
Vice President, Quality, Consumables

Enclosures:
- Customer Response Form (see below)

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URGENT: FIELD SAFETY NOTICE – RESPONSE FORM

Medex Infusion Extension Sets, Model MX618CZ

10th July 2023

Check your inventory and complete the information below, even if you do not have the affected product. *Failure to complete all sections of this page may result in improper, delayed or denied credit.*

Please return the completed form to EMEA-Quality@icumed.com, Smiths Medical Customer Service and your local sales representative.

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name and Title of Person Completing this Form	
Signature of Person Completing this Form	
Date	
If Purchased through a distributor, please list distributor name/location here for traceability purposes	

Please select one:

☐ **I have NO affected products (complete and return this form to the e-mail address above)**

☐ **YES, I have affected products**

If you have affected product on hand, please complete table below:

TABLE 1

List Number	Lot Number	Quantity in inventory	PO, debit memo or invoice
MX618CZ	**4306091**		

If you have distributed the product further, please complete table below with collated information received from your custome rs and respond to ICU Medical with the overall information.

TABLE 2

List Number	Lot Number	Quantity destroyed locally by customer	Quantity returned to distributor
MX618CZ	**4306091**		

☐ I have followed the instructions provided to me and I will **destroy** affected products on site (complete and return provided Certificate of Destruction to the email addresses on the certificate).

☐ I have followed the instructions provided to me and I will contact my Smiths Medical CS Representative to make arrangements to **return** the affected products.

☐ I have followed the instructions provided to me. If affected product is not being returned, please explain below:

Adverse events and complaints associated with the use of this product should be reported and emailed to the Competent Authori ty or to Smiths Medical's Global Complaint Management Department at globalcomplaints@icumed.com.