



W. Droh GmbH · Dammweg 11 · D-55130 Mainz

www.droh.de

Contact: [REDACTED] Phone: [REDACTED] Fax: [REDACTED] E-Mail: [REDACTED] Date: 11.02.2020 Customer-No.:

Urgent safety notification

concerning

TIVA Infusion set 17-TV-02-C, REF
211062W1B, LOT 19/501513

Internal number:

Dear Sirs and Madams,

With this letter you will receive urgent information about the recall of the TIVA Infusion Set 2 of Shandong Lee Med Technology Co., Ltd. with the request for the fastest possible forwarding to the relevant departments and users of your facility and for the initiation of the steps described below.

Description of the fault:

There is a possibility that environmental stress cracking may occur, especially when using lipid-containing anesthetics, which can then lead to leakages on the TIVA set. A leakage of liquid or an entry of air cannot be ruled out. In the worst case, the anesthesia can be interrupted.

You have also received items affected by the recall: See attachment.

Please take the appropriate steps:

1. Please inform all users of the products mentioned and other responsible persons in your organization.
2. Please check all items in stock for the specified batch numbers (LOT). Please stop using the goods with the named batch (LOT) immediately.
3. If necessary, forward this information to third parties to whom you have supplied or made available the items.
4. Send the completed return form by post, fax or email no later than February 28, 2020.

The Federal Institute for Drugs and Medical Devices (BfArM) has already received a corresponding notification.

We will be happy to answer any questions you may have at any time.

Sincerely yours

Wolfram Droh GmbH

[REDACTED]
[REDACTED]

Attachments:

- Overview of the delivered articles
- feedback sheet



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Feedback sheet

RSVP until 28. February 2020 by Fax +49 6131 62319-11 or email verkauf@droh.de

Inspection of own stock (including probably customer's stock)

Please check one of the following options:

- The inspection of stock shows no items in stock
- The inspection shows following items in stock:

REF	LOT	Quantity

Instructions:

Please complete the chart below to fasten the process.

Please do not arrange a return shipment before prior notification.

Name of customer:	
Name of organization:	Telephone / Email address:
Date & Signature:	Stamp