



Urgent product safety information

200833547

regarding

Karl Storz: Plastic container for sterilization
Art. no. 39402AS and 39406AS

2020-10-22

Product description: Plastic container for sterilization

Article numbers: 39402AS and 39406AS

Batch numbers: all

Sender: Karl Storz SE & Co. KG,
Dr.-Karl-Storz Straße 34,
78532 Tuttlingen, Germany

Addressee:

All users, operators, and safety officers at clinics and hospitals

Identification of the medical devices concerned:

Sterilization container – plastic container for sterilization, article number 39402AS, batch numbers: all

Sterilization container – plastic container for sterilization, article number 39406AS, batch numbers: all

Description of the problem including the identified cause:

Routine revalidations identified some microbial growth under half-cycle conditions when these plastic containers were used in conjunction with Sterrad 100 NX in the DUO cycle in the case of endoscopes with a channel length of more than 850 mm.

There is no possibility of danger to patients/users/third parties as the partial microbial growth occurred under half-cycle validation conditions. An endoscope intended for use on a patient would always undergo a full sterilization cycle.

What measures are to be taken by the addressee?

According to our records, you have been supplied with at least one of the products listed above and are therefore affected by this action.

Please read this letter carefully and take the following measures:

1. When sterilizing one of the following endoscope models from KARL STORZ (11004BI1, 11301AA1, 11301AAD1, 11301BN1, 11301BND1, 11301BNX, 11302BD1, 11302BD2, 11302BDD2, 11302BDX, 11303BNX, 11304BC1, 11304BCX, 11340BC1, 11161EL2) in one of the sterilization trays (39402AS or 39406AS) in the Sterrad 100 NX, the DUO cycle must not be used.
2. The FLEX cycle should be used instead.
3. Ensure that your employees receive appropriate training regarding this new procedure and the enclosed reprocessing instructions.
4. Fill in the attached reply and return it to the indicated address. With this reply, you confirm that your staff have received training regarding the new procedure.
If the corresponding products are no longer in your stocks on site, please return the appropriately completed reply to us anyway. This will enable us to update our records, and you will avoid receiving further unnecessary correspondence about this subject from us.
5. No further action is required for patients who have received treatment.
6. Send the completed response form to the fax number, e-mail address, or mailing address on the form by November 20, 2020.

If you have any questions about this action, please get in touch directly with the contact person listed below.

We hereby confirm that the relevant national authorities in your country have been informed about this safety-related corrective action.

Thank you in advance for your prompt response to this matter. We apologize for any inconvenience caused.

Contact:

Robert Herz
Karl Storz SE & Co. KG
Tel.: +49 07461 708 7348 (during business hours)
Fax: +49 07461 708 45581

Sincerely,

A handwritten signature in blue ink, appearing to read 'Robert Herz', is positioned below the 'Sincerely,' text.

p.p.
Robert Herz
Karl Storz SE & Co. KG

Customer response form: 200833547

Karl Storz: Plastic container for sterilization

Product description: Container for sterilization
Article numbers: 39402AS and 39406AS
Batch numbers: all
Sender: Karl Storz SE & Co. KG,
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78532 Tuttlingen, Germany

Customer no. _____
Hospital _____
ZIP, town/city _____
Contact _____
Phone no. _____

- I confirm that I have read and understood the product safety information 200833547 and that I have implemented it accordingly.
- We do not have any of the listed products in our stocks

Name: _____
Signature: _____
Date: _____

We have passed on affected products to the following facilities:

Contact details for facility

Please send this form to:
vigilance@karlstorz.com

or

Fax: +49 07461 708 45581

or by mail to

KARL STORZ SE & Co. KG
Attn. Robert Herz
- Department Head Vigilance -
Dr. Karl-Storz-Str. 34
78532 Tuttlingen, Germany