Urgent Field Safety Notice for Leica ASP6025

Attention: Lab Manager

Dear Sir/Madam,

11/12/2012

With this field safety notice we would like to inform you about an incident we have experienced with our tissue processor, Leica ASP6025. You have received this notification as you have received one or more of the units concerned.

Details on affected devices:

Leica ASP6025, Tissue Processor Serial number

162, 163, 168-171, 183, 184, 200-295, 297, 299, 301, 303, 305, 307, 309, 311, 313, 315, 317, 319, 321, 323, 325, 327, 329, 331, 333, 335, 337, 339

Description of the problem:

The Instruction for Use 1v9 RevF and all previous versions does specify wrong dimensions for the Ready To Use (RTU) bottles from other suppliers than Leica. In case of a pressure failure of the device in combination with a bottle with wrong dimension, overflow can cause contamination of reagents. Additionally the current instruction for use does not highlight the importance to check the filling levels of all reagent bottles (RTU and system bottles) prior to every process run.

Without this important information risk of tissue damage or loss is possible.

Advice on actions to be taken:

As a preliminary countermeasure we advise that you only use the Leica RTU bottles (14049543542) already being supplied as a standard delivery item with the ASP6025 to you.

Additionally prior to each process run reagent bottle levels need to be checked and corrected if necessary.

Robert Gropp · RAQA Manager · CHS · Leica Biosystems v.1.1
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For further details, please read attached the attachment to the Instruction for Use (Attachment 2012-04 ASP6025 1v0 RevB, 12/2012) with additional information on optimal bottle handling.
The above countermeasure should be carried out upon receipt of this letter.
Your assistance is appreciated and necessary to prevent possible loss of patient tissue.

In parallel, technical alternatives are being assessed.

Transmission of this Field Safety Notice:
This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.
Please maintain awareness of this notice and resulting action to ensure effectiveness of the corrective action.

Contact reference person:
Should you have any questions, please contact
(Name/ address/ contact details of the local RA/QA representative will be added here).

Please complete and return the enclosed response form within ten working days.

We are sincerely sorry for any inconvenience caused by this issue.

Best regards,

Robert Gropp
RA/QA Manager
Leica Biosystems Nussloch GmbH
(The undersign confirms that the FSN is being made with the knowledge of the relevant Health Authorities)

FIELD SAFETY NOTICE RETURN RESPONSE FORM

Leica ASP6025, Tissue Processor

Please record the serial number of your device(s):

_____

_____

Please check only appropriate boxes.

- ☐ I have read and understand the Field Safety Notice and supplemental sheet 2012-04 ASP6025 1v0 RevB, 12/2012 provided.
- ☐ I have identified and notified my customers to whom this product was shipped or may have been shipped. (specify date and method of notification):

  _____

  _____

  Please use additional paper in case space is not sufficient

Name: _____
Title: _____
Phone: _____
Firm Name: _____
Address: _____
City/State: _____

Please fax completed response form within ten working days to 0049/(0)6224 143 5345

Or mail to: Leica Biosystems Nussloch GmbH
Attn. Robert Gropp
Heidelberger Str. 17-19
69226 Nussloch - Germany

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