URGENT FIELD SAFETY NOTICE

Product Name: **HistoCore PELORIS 3**
UDI: **09349458004804**
FSN Reference: **2025-01-01**
FSN Type: **New**
FSCA Reference:

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19 August 2025

Attention: Pathology Department

Details on affected devices:

This Field Safety Notice (FSN) applies to the HistoCore PELORIS 3 instrument supplied and installed at your site by Leica Biosystems, as listed in the below table.

Instrument Model Number	Instrument Serial Numbers
45.0001	45220586

Intended use of the instrument:

The HistoCore PELORIS 3 Rapid Tissue Processor is a dual retort rapid tissue processor used to prepare tissue samples for sectioning by transforming fixed samples into wax embedded samples by exposing the tissue samples to a sequence of reagents in the processing retorts.

Description of the problem:

Leica Biosystems has become aware of a reagent leakage issue associated with a tubing connection to a manifold in a small number of the HistoCore PELORIS 3 instruments. Our investigation has identified that the root cause of the leakage is due to isolated instances of incorrectly assembled fittings on a batch of manifolds.

Leakage may expose instrument operators and other laboratory personnel to toxic reagents and pose a slip hazard. In case of significant leakage, tissue processing may be impacted.

Leica Biosystems has decided to conduct an urgent medical device field action to inspect and check the retention of the tubing to the manifold for all instruments with manifolds from the affected batch.

ACTIONS REQUIRED

1. If leakage from the instrument is observed in the drip tray or surrounding the instrument, please follow your laboratory's leakage containment/safety protocol. If a protocol is running, wait for the run

URGENT FIELD SAFETY NOTICE

to finish, switch off the instrument and contact your local Leica Biosystems representative immediately.

2. If no leakage has been observed from the instrument, continue using it as normal. Conduct routine monitoring for leakage until the on-site inspection is completed.

3. Your local Leica Biosystems representative will contact you to schedule an onsite inspection of your instrument/s for replacing the tubing and/or density meter manifold if needed.

4. **Confirm Receipt of FSN**

   Please confirm receipt of this FSN by signing and dating the attached Field Safety Notice Acknowledgement Form by email to the following email address within 2 weeks of receiving this notice:

   lbsmel.rfa@leicabiosystems.com

Please contact your local Leica Biosystems representative immediately if you have any questions or concerns.

Transmission of this Field Safety Notice:
Kindly pass this notice to all those within your organisation who need to be aware of this issue or to any organisation where the potentially affected instrument/s have been transferred.

Your cooperation in this matter is greatly appreciated and we sincerely apologise for any inconvenience this may have caused.

Yours sincerely

Yuvesh Jain
Manager, Regulatory Compliance
Leica Biosystems Melbourne
Email: yuvesh.jain@leicabiosystems.com

URGENT FIELD SAFETY NOTICE

FIELD SAFETY NOTICE ACKNOWLEDGEMENT FORM

HistoCore PELORIS 3

The following **HistoCore PELORIS 3** serial number/s from above are at my site:

Model Number	Instrument Serial Number(s)
45.0001	

I hereby acknowledge receipt of the Leica Biosystems Field Safety Notice on behalf of:

_____
Facility Name (Please Print)

_____
Facility Address (Please Print)

_____
Facility Contact Person (Please Print)

_____ _____
Signature Date

Please scan and email the completed form to:

Email: lbsmel.rfa@leicabiosystems.com