

2023-05-16

FIELD SAFETY NOTICE

for Hamilton Subsidiaries HAMILTON CO-RE Tips

REF	Product name
235948	CORE TIPS (50µl), FILTER
235979	CORE TIPS 50µl, FILTER, STERILE
235697	CORE TIPS (50µl), FILTER

Affected Lot numbers
7042035, 7042036, 7042085, 7042085, 7042128, 7042173, 7112236, 7112362, 7112363, 7112364, 7112365, 7112385, 7112386, 7112387, 7112388, 7112389, 7112390, 7112391, 7112544, 7122434, 7122435, 7122436, 7122437, 7122438, 7122439, 7122440, 7122443, 7123374, 7122507, 7122509, 7122510, 7122511, 7132512, 7132514, 7132515, 7132861, 7132862, 7133759, 7133205, 7133763, 7133206, 7133764, 7133207, 7143964, 7133208, 7143771, 7143947, 7143209

Recipients:	<ul style="list-style-type: none"> All laboratory facilities using HAMILTON CO-RE Tips All distribution partners of HAMILTON CO-RE Tips and their service engineers.
Time frame for distribution partners	<ul style="list-style-type: none"> The authorities must be notified within 10 days of receiving the safety notice. The field safety notice should be translated into the local language and distributed to customers if required at local level.

Dear Hamilton Subsidiary,

Hamilton Bonaduz AG is announcing for the products listed above a Field Safety Notice. This letter contains important information that needs your attention.

ISSUE	<p>Hamilton Bonaduz AG has become aware of a quality issue related to the storage of CO-RE Tips, which showed up after approximately 2 years. CO-RE Tips with above listed REF numbers and Lots may show a crack in the section of the tip where the filter is located</p> <p>As root cause the filter has been identified. Said filter is being inserted into to the tip during production. Affected tips have been produced using filters temporarily from a second supplier. We assume the crack is being caused by the harder material the filter is made of. This results in a higher tensile stress on the tip wall caused by the filter after insertion. This may finally lead to a crack in the tip wall.</p>
MALFUNCTION	<p>If the defect tips are used for pipetting the crack causes the tips to lose fluid which can lead to:</p> <ol style="list-style-type: none"> 1. Single sample cannot be analyzed / is evaluated incorrectly -> no result (for user of product/service provider or patient). 2. Contamination of the working environment (interior Instrument) -> further samples are contaminated, mixing of samples

	3. Not "questioned" re-execution / repetition of the test with again (majority) incorrect tips, with consequence 1. or 2.
ACTION	<ul style="list-style-type: none"> • Identify any of affected lots in your warehouse • Immediately transfer these products to your restricted area for blocked goods • Inform any customers / users of the affected products to block the affected products • Either return affected products to Hamilton or destroy these and have us a proof of destruction as objective evidence • Hamilton will replace the affected products free of charge upon return resp. proof of destruction and request
RESOLUTION	The root cause analysis has shown that the cracking of above listed tips was merely caused using the filters supplied by the second supplier. Hence, no further actions are required.

The national Competent Authority has been informed of this Field Safety Corrective Action.

Immediately share this information without undue delay with your customers and retain this notification as in your Quality System documentation. Please ask your customers for a confirmation of the actions taken.

Please complete and return the enclosed response form best within 10 days no later than 2023-06-20 June so that we are assured you have received this important communication.

Manufacturer: Hamilton Bonaduz AG
Via Crusch 8
CH-7402 Bonaduz
Switzerland

Contact: Hamilton Bonaduz AG
ROB QARA
Via Crusch 8
CH-7402 Bonaduz
Tel. +41 58 610 10 10
Email: vigilance.rob.ch@hamilton.ch

We appreciate your support in this matter and sincerely regret any inconvenience you may experience as a result of the issue described above

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Please keep this Field Safety Notice with your HAMILTON Documents.

Confirmation - For Hamilton Subsidiaries**HAMILTON CO-RE Tips field safety notice (FSN-2023-01)****Malfunction:**

1. Single sample cannot be analyzed / is evaluated incorrectly -> no result (for user of product/service provider or patient)
2. Contamination of the working environment (interior instrument) -> further samples are contaminated, mixing of samples
3. Not "questioned" re-execution / repetition of the test with again major incorrect tips, with consequence of 1. or 2.

Required actions:

- Immediately transfer these products to your restricted area for blocked goods
- Inform any customers / users of the affected products to block the affected products
- Either return affected products to Hamilton or destroy these and have us a proof of destruction as objective evidence

This confirmation should be returned once all the end customers have returned signed confirmation.

Number of customers impacted: _____

Number of customers who returned the confirmation: _____

By signing this document, we confirm that all affected customers have been informed of this field safety notice and all affected customers have confirmed receipt thereof and the required actions have been performed.

Name:

Subsidiary:

Affected products returned or destroyed (To be filled out by the Subsidiary):

Lot	Number of Blisters	Lot	Number of Blisters

No affected **Lot** found

Date:

Signature:

Sign this information sheet. The document " Confirmation - For HAMILTON Subsidiaries " must be completed and sent by email to vigilance.rob.ch@hamilton.ch best within 10 days no later than 2023-06-20. (Address to be used for this case only)