

# Urgent Field Safety Notice

## SBN-CPS-2019-018

CPS / Point of Care Cardiac

Version 1

September 2019

## Non-systemic occurrence of defective pipettes

<b>Product Name</b>	Syringe 150 µl 5 PC. Japan Cardiac pipettes 150 µl 20pc (int.) Syringe 150 µl 5 PC
<b>Product Description</b>	150 µl Pipettes
<b>GMMI / Part No</b>	Syringe 150 µl 5 PC. Japan 05904528001
<b>Device Identifier</b>	Cardiac pipettes 150 µl 20pc (int.) 11622889190 Syringe 150 µl 5 PC. 11740130001
<b>Production Identifier (Lot No./Serial No.)</b>	Lot independent
<b>SW Version</b>	N/A
<b>Type of Action</b>	Field Safety Corrective Action

Dear Valued Customer,

In the past months we have received 9 customer complaints worldwide for Cardiac Pipettes (out of more than 11 million distributed single syringes). The following issues were observed: 8 cases where the needle came off the pipette and 1 case where the needle became stuck in a sample tube. The manufacturer has carried out an investigation and confirmed these findings. In all related complaints the issue was detected by the user and no injury occurred.

Due to the residual medical risk associated with this issue, customers using the affected product must be informed using this FSN.

# Non-systemic occurrence of defective pipettes

## Actions taken by Roche Diagnostics

Roche will update the operator's manual for **cobas h 232** as well as the method sheet of the Trop T visual strip. In order to provide guidance how to recognize and handle a defective pipette, the warning message below will be added:

### WARNING

Before use, visually check if the packaging of the Cardiac pipettes and/or the pipettes are intact. If the needle falls off or gets stuck during use, do not try to re-cap it. Stop using the pipette immediately and dispose of it in a sturdy sharps container (in accordance with applicable local regulations and directives and your facility's guidelines).

## Actions to be taken by the customer/user

Before use, visually check if the packaging of the Cardiac pipettes and/or the pipettes are intact. If the needle falls off or gets stuck during use, do not try to re-cap it. Stop using the pipette immediately and dispose of it in a sturdy sharps container (in accordance with applicable local regulations and directives and your facility's guidelines).

## Communication of this Field Safety Notice (if appropriate)

This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the potentially affected devices have been distributed/supplied. (If appropriate).

Please transfer this notice to other organizations/individuals on which this action has an impact. (If appropriate).

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action. (If appropriate).

### **The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:**

*Include if applicable:* The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We apologize for any inconvenience this may cause and hope for your understanding and your support.

<closing salutations>,

### Contact Details

*To be completed locally:*

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com