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Date: 3<sup>rd</sup> October 2016

**URGENT: MEDICAL DEVICE RECALL**

Dear Valued Research Instruments' Customer

Research Instruments has identified a manufacturing fault with a specific LOT of the EZ-Tip product that could result in the device failing to perform its intended purpose. Our records show that this lot was shipped to your facility. RI is undertaking a voluntary recall of this product.

**Affected product:**

Part number	Product description	LOT number	Expiry date
7-72-2145/5	145µm EZ-Tip (Vial of 20)	91148	March 2018 (2018-03)

The EZ-Tip® is for denudation, ie removing the cumulus from an oocyte prior to the assisted reproduction techniques of Intracytoplasmic Sperm Injection (ICSI) and In Vitro Fertilisation (IVF), and effecting dish to dish transfer of cells, embryos and oocytes.

Our records show that ... boxes of the above part number were despatched on ..././....., your reference PO ....., our reference INV.....

Research Instruments recommends that the use of this LOT number is immediately discontinued and any remaining stock is disposed of.

Please complete the attached **Acknowledgement and Receipt Form** to confirm receipt of this letter and your understanding of the instructions. This form will also confirm to us the quantities disposed. Once this form has been received replacement of the product will be arranged.

In the meantime, if you have any questions or concerns, please contact Research Instruments Customer Service on 01326 372 753 or contact us via e-mail at [john.mitchell@research-instruments.com](mailto:john.mitchell@research-instruments.com)

Please accept our apologies for any inconvenience this has caused.

Thank you for your cooperation

John Mitchell  
Quality and H&S Manager

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**Acknowledgement and Receipt Form: Response is required**

Please complete this form and e-mail a copy to [john.mitchell@research-instruments.com](mailto:john.mitchell@research-instruments.com)

Name of Your Company :

Address of Your Company :

Contact Name/Title :

Phone Number :

E-mail Address :

I have read and understand the recall instructions provided in the 03/10/2016 letter. Yes\_\_No\_\_

Signature:\_\_\_\_\_ Name:\_\_\_\_\_

**Affected Product Information:**

Part number	Product description	Batch number	Expiry date
7-72-2145/20	145µm EZ-Tip(vial of 20)	91148	2018 (2018-06)

Quantity in inventory: \_\_\_\_\_

Quantity destroyed: \_\_\_\_\_

Return Response Box:

Please provide any additional information, if applicable

I confirm that the quantities noted above have been disposed of:

Signature:\_\_\_\_\_ Name:\_\_\_\_\_