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11 March 2016

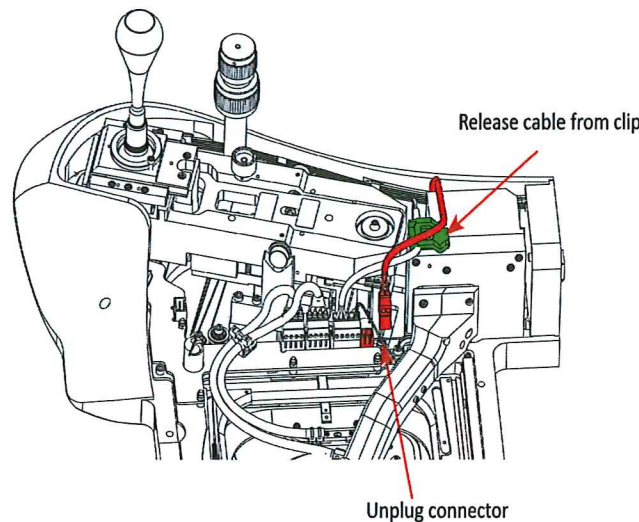
**URGENT: MEDICAL DEVICE RECALL**

Dear Valued Research Instruments' Customer

Research Instruments is voluntarily recalling the power supply cable for the **Integra 3™ micromanipulator**. Research Instruments internal testing has discovered a minor materials fault with the power supply cable (2-54-031). Our records show the affected products were shipped to your facility.

The Integra 3 micromanipulator has been designed to precisely position microtools under a microscope whilst maintaining specimen temperature during Assisted Reproduction Techniques (ART) such as Intracytoplasmic Sperm Injection (ICSI) and Intracytoplasmic Morphologically-selected Sperm Injection (IMSI).

In rare instances, the power supply cable may cause the loss of power to the heating control of the Integra 3 and the temperature function to be disabled. In order to mitigate any chance of down time for your customers' Integra 3 micromanipulator, we recommend this power supply cable is replaced by one of your trained technical engineers. We anticipate this correction will take approximately 10 minutes depending on accessibility.



To initiate the replacement of the power cable, please follow the steps below:

1. Acknowledge receipt of this letter by completing the attached **Acknowledgement and Receipt Form**
2. Review your sales and traceability records to identify users of the Integra 3 model. Please note, you are contractually obligated to maintain traceability records for the sale of all RI products and this information should be easily available.
3. Promptly contact all Integra 3 users and inform them of this Correction Notification
4. Promptly arrange the replacement of the cable on each Integra 3 by one of your trained technical engineers within 3 months of the date of this letter.
5. Record each replacement on the Product Correction Completion Form (PCCF) enclosed. The serial number of each Integra 3 can be found on the back panel.



6. Send a copy of the completed PCCF to Research Instruments within 3 months of the date of this letter.

Instructions (2-54-031-IM) are enclosed with the replacement cables. These instructions and a film showing the replacement process can also be downloaded from the Research Instruments Distributor Website (<http://distributor.research-instruments.com>) and the film can be also viewed at <https://youtu.be/5kclgyMh4Vg>.

If you require more cables, or any advice or assistance in order to complete any aspect of this correction, then please contact [service@research-instruments.com](mailto:service@research-instruments.com).

If you have any questions or concerns please contact Research Instruments Customer Service on +44 (0) 1326 372 753 (Monday through Friday 8.00 – 16.30 GMT) or contact us via e-mail at [service@research-instruments.com](mailto:service@research-instruments.com).

Thank you for your cooperation

John Mitchell  
Quality and H&S Manager



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

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

Name of Your Company :

Address of Your Company :

Contact Name/Title :

Phone Number :

E-mail Address :

**Affected Product Information: Include information that is applicable for affected product.**

Part Number	Product Description	Serial Number
6-54-100		
6-54-110		
6-54-150		
6-54-160		

Please inform us of any anomalies in this list ie. serial numbers not accounted for, etc.

I have read and understand the recall instructions provided in the 7th March 2016 letter.

Please tick            **Yes**\_\_\_\_            **No**\_\_\_\_\_

If you have any questions or concerns please contact Research Instruments Customer Service on +44 (0) 1326 372 753 or contact us via e-mail at [service@research-instruments.com](mailto:service@research-instruments.com).

**Signed:**

**Date:**

**Print Name:**

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**PRODUCT CORRECTION COMPLETION FORM  
 (PCCF)**

Please complete this form and send a copy to [service@research-instruments.com](mailto:service@research-instruments.com). We recommend you retain a copy for your own records.

Name of Your Company :  
 Address of Your Company :  
 Contact Name/Title :  
 Phone Number :  
 E-mail Address :

Please record the following Integra 3 product information details for each power supply cable replacement.

End User Name and Address	Integra 3 serial number	Date of Replacement

(More lines over page)

Please inform us of any anomalies in this list ie. serial numbers not accounted for, etc.

Were there any adverse events associated with the replacement of this power cable? YES \_\_\_ NO \_\_\_

If YES, please provide details here:

Signed:  
 Print Name:

Dated:

