

Bickland Industrial Park, Falmouth, Cornwall, TR11 4TA, UK
Tel: 01326 372753 [International +44 1326 372 753]
Fax: 01326 378783 [International +44 1326 378 783]
e-mail: sales@research-instruments.com
www.research-instruments.com

11 March 2016

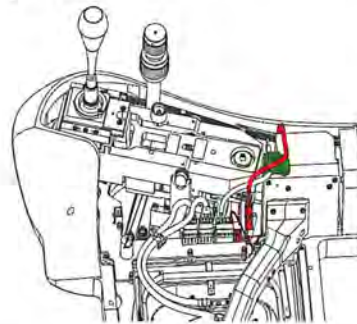
URGENT: MEDICAL DEVICE RECALL

Dear Valued Research Instruments' Customer

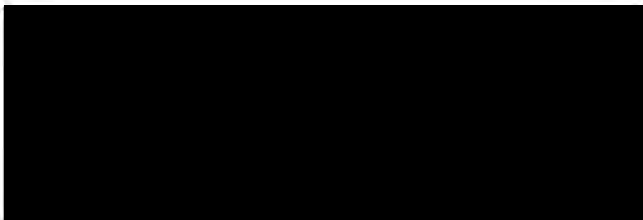
Research Instruments is voluntarily recalling the power supply cable for the **Integra 3™ micromanipulator**. Research Instruments internal testing has discovered a minor materials fault with the power supply cable (2-54-031). Our records show the affected products are installed at your facility.

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, this cable may cause the loss of power to the heating control of the Integra 3 and the temperature function being disabled. In order to mitigate any chance of down time for your Integra 3 micromanipulator, we have already replaced your power supply cable during a scheduled service visit and you can therefore consider this correction complete.



Please complete the attached **Acknowledgement and Receipt Form** to acknowledge receipt of this communication. If you have any questions or concerns, please contact Research Instruments Customer Service on **01326 372 753** or contact us via e-mail at service@research-instruments.com.





Acknowledgement and Receipt Form: Response is required

Please complete this form and e-mail a copy to 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 11th March 2016 letter.

Please tick **Yes**____ **No**____

I confirm Research Instruments Service Department has carried out this replacement on date: _____ and there were no adverse events associated with the replacement of this power cable.

If you have any questions or concerns please contact Research Instruments Customer Service on 01326 372 753 or contact us via e-mail at service@research-instruments.com.

Signed:

Date:

Print Name:

11 March 2016

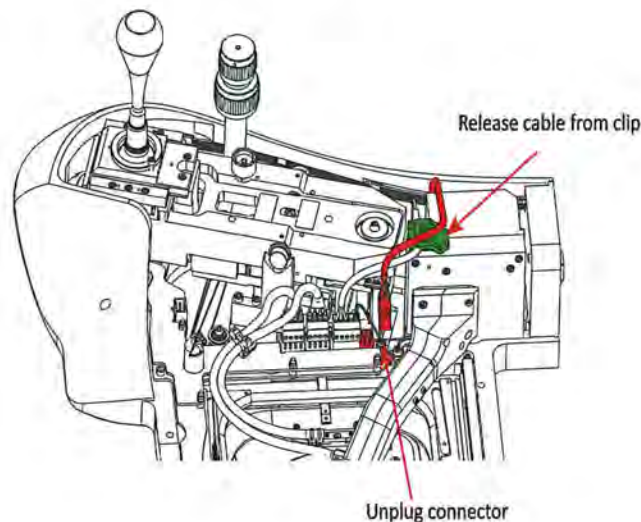
URGENT: MEDICAL DEVICE RECALL

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.



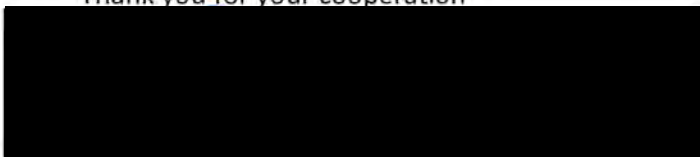
6. Send a copy of the completed PCCF to Research Instruments within 3 months of the date of this letter.

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.

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.

Thank you for your cooperation





Acknowledgement and Receipt Form: Response is required

Please complete this form and e-mail a copy to 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 11th 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.

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. 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:

