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URGENT: FIELD SAFETY NOTICE

Commercial name of the affected product: PlasmaKinetic SuperSect™/PK SuperSect Instrument
FSCA Identifier: 2183680-08/05/09-001-R
Type of Action: Field Safety Corrective Action

August 6, 2009

Attention: Dear Valued Gyrus ACMI customer,

Details on affected devices:
PlasmaKinetic SuperSect™/PK SuperSect Instrument
REF 744200
Lot Numbers: M0809094 and M0809062

We wish to bring to your attention an issue concerning the Gyrus ACMI PlasmaKinetic SuperSect/PK SuperSect Instrument. .

Description of the problem:
There have been field incidents, involving the above-referenced lot numbers, where the product has sparked or shorted at the cable/loop junction or where a part has detached during the procedure. Gyrus ACMI is not aware of any patient injuries associated with these incidents but cannot ensure that there is no risk to the patient or user. Accordingly, Gyrus ACMI is conducting a field safety corrective action (recall) of the affected product.

Our records indicate that you may have received one or more shipments of affected product. **Action to be taken by the user:**

1. Cease any further use of the affected product
2. Remove all of the affected product from your stockrooms and quarantine it.
3. Call your customer service representative (XXXXXXX) to obtain a Return Goods Authorization. This will allow you to return the product to Gyrus ACMI with no charge to you.
4. Return the affected product at the address indicated in the enclosed reply form.
5. Complete the reply form and return it to the attention of XXXXXX. at the indicated fax number

Please note that even if there is none of the affected inventory present in your stockrooms, Gyrus ACMI requires that you complete and return the enclosed reply form. If any inventory from the lot numbers is present, Gyrus ACMI will arrange for the return shipment and will replace the goods at no charge to you.

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GYRUS ACMI

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– Olympus

Transmission of this Field Safety Notice:
This notice needs to be passed on to all those who need to be aware within your organization, or to any organization where the potentially affected devices have been transferred.

Contact reference person:
[Please enter contact details from the distribution point here]

Authorised European Representative:
Gyrus Medical Limited
Fortran Road, St Mellons, Cardiff, CF3 0LT, UK

[redacted] Manager International Regulatory Affairs
Email: [redacted]@gyrusacmi.com
Telephone: +44-29-20776393; Facsimile: +44-29-20776301

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We appreciate your cooperation and apologize for any inconvenience this may cause. We value our relationship with you and are constantly striving to provide you with the highest quality products. If you have any questions, please do not hesitate to contact your customer service representative.
Sincerely,

[redacted]
Vice President, Regulatory Affairs

Enclosure