Corrective and Recall Action

As per recommendations in Health Canada's **Medical Device Regulations (SOR/98-282)** and **Guidance on Investigation of Reported Medical Device Problems (GUI-0054)** Glia's Recall Protocol includes the recommended steps for immediate removal of any product deemed defective and/or dangerous. Glia's standard reporting form is adopted from Health Canada's **Guidance on Recall Policy (POL-0016).** Glia's Corrective and Recall Action is also adopted from Health Canada's **Guide to Recall of Medical Devices (GUI-0054).**

In the unlikely event of a correction or recall, the following steps are to be followed:

1) If necessary, a mandatory reporting form will be filled out and sent to Heath Canada. The Mandatory Problem Reporting Form can be found online at:

http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/medeff/report-declaration/md-mm_form-eng.pdf

2) In the event of a correction or recall, Glia will inform the Medical Devices Unit immediately with the following information:

    a) The name of the recalled product and, where applicable, the identifying model designation, serial number, code, lot number and any other means of identification.
    b) The total quantity of the recalled product originally in his possession.
    c) The total quantity of the recalled product that had been distributed up to the time of the recall.
    d) Area of the distribution of the recalled product by province and, if exported, by country.
    e) The quantity of the recalled product still in his possession.
    f) The reason for initiating the recall.

    Information will be reported verbally, and then confirmed in writing to:

Phone: 416-973-1596
Email: ONT-MED@HC-SC.GC.CA

3) Glia will post a recall notice on Glia's website, and immediately send a correction or recall notification via email to all of Glia's subscribers and relevant contacts.

4) Glia will then use the distribution records for the affected products to immediately target medical professionals in the areas (ie. hospitals, and clinics) around which the device was distributed.

5) Glia will disseminate recall information to the hospitals and medical centres impacted by the faulty device in the form of a recall notice (poster).

6) The recall notice, as created in Appendix 1, will specify the date of the recall, the information about the specific device or devices, details of the recall, instructions to stop using the

product immediately, and contact information in order to further process a refund or replacement of the device.

7) If it is determined that not enough affected persons are informed about the recall, Glia will then take steps to inform the media about the recall. Glia will primarily send out information to print media sources, radio, and - if necessary - television.

For more information, please see:

Guide to Recall of Medical Devices (GUI-0054)

http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui-0054_recall-retrait-doc-eng.php

Company Logo
Company Contact Information

Recall Notice

Date:

Devices affected (list):

Details of the recall (ie. What are the reported issues and complaints).

Instructions:

Stop Using Product Immediately

or

Specific Corrective Actions

For information about the recall, including replacement and/or reimbursement of costs for device, please see:

<u>Contact information</u>:

Glia Website
Glia Email
Tarek Contact Information