Reference No. _____

Standard Reporting Form

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 product safety and quality assurance protocol includes the recommended "standard reporting form for the recording of problem report information."[1] Glia's standard reporting form is adopted from Health Canada's **Guidance on Investigation of Reported Medical Device Problems (GUI-0054), Appendix 3.**

Date:
Date complaint was received:

Reporter Information:

Name:
Address:
Contact Information:
H:
C:
E:

Complainant Information:

Name(s) of individual(s) filing complaint/ problem:
Contact information for individual(s):
H:
C:
E:

Device Information:

Name of the device:
Device Identifier:
Lot number:

Problem/ Complaint Information:

Most recent date of problem occurrence:
Summary of the problem:

_____

Specific Details:

Did the device cause any form of harm to the patient, including but not limited to: injuries, adverse reactions, allergic reactions?
Y N

If **YES**, complete questions 1 & 2, if **NO**, continue to **User Experience**:

1) Explain the problem:

2) Did the patient have a medical condition or conditions that could have caused similar symptoms or problems?
Y N
If yes, explain:

User Experience:

Is the complainant a medical professional using the device for the stated medical use?
Y N

If **NO**, who was using the device, and how was the device being used?

Device Information:

Explain the device use:

Who:
Where:
When:
How:

How old is the device?

How frequently was the device being used (eg. daily, monthly, annually)?

Were there previous problems with the device prior to the current reported problem?
Y **N**

If **YES**, explain:

How frequently was the device problematic (eg. one time which rendered it unusable, or multiple times)?

How and where was the device being stored?

Was the device damaged in any way by the user (eg. dropped or burned)?
Y **N**

If **YES**, explain:

Was the device attached to any other equipment at the time?
Y **N**

If **YES**, explain:

Was the product modified in any way before, during, or after its use:
Y **N**

If **YES**, explain:

Was the product cared for as per the listed guidelines on the device packaging?
Y N

If **NO**, explain:

If Applicable: Other (eg. details, complaints, or problems) that are not covered by the standard reporting form: