



## Medical Device Incident Reporting Form

Client Name: \_\_\_\_\_

Address: \_\_\_\_\_

Phone: \_\_\_\_\_ DOB: \_\_\_\_\_ Sex: \_\_\_\_\_

Attending Physician: \_\_\_\_\_

Diagnosis: \_\_\_\_\_

Allergies: \_\_\_\_\_

### Event Information

Date of Event: \_\_\_\_\_ Date Reported: \_\_\_\_\_

Location: \_\_\_\_\_

Description of Event: \_\_\_\_\_

\_\_\_\_\_

Specific Injury Incurred: \_\_\_\_\_

Event Results (death, injury, etc.): \_\_\_\_\_

Other relevant devices in use at time of event: \_\_\_\_\_

Was device/equipment being operated as intended?  Yes  No

If no, explain:

\_\_\_\_\_

**Date reported to FDA (if applicable) :** \_\_\_\_\_

**Date reported to Manufacturer:** \_\_\_\_\_

Status prior to incident:  Stable  Serious  Critical

**Submitted By:** \_\_\_\_\_ **Date:** \_\_\_\_\_