ECRI's Medical Device Incident Investigation Form

The following form is a data-collection tool designed to capture relevant information concerning a device-related incident and investigation, including the information required to be reported to FDA. This form may be reproduced for use in your institution. The completed form should not be photocopied or filed in the patient's medical record.

Medical Device Incident Investigation Form

CONFIDENTIAL — FOR INTERNAL RISK MANAGEMENT PURPOSES ONLY

DO NOT PHOTOCOPY OR FILE IN MEDICAL RECORD

Case Identifier No. _____

I. DEVICE INFORMATION

Record for each device involved in incident, including disposables. Use separate forms as necessary.

Manufacturer name _____

_____

Brand name _____

_____

Generic product name _____

_____

Model number _____

Catalog number _____

Serial number _____

Lot number _____

Internal equipment control number _____

Expiration date _____

Purchase date _____

Labeled for single use? _____

Previously used? _____

Implanted device? _____

Implantation date _____

Reusable device? _____

Cleaning/sterilization method used _____

_____

Collect the following: purchase contract, package insert, user/operator manual, maintenance contracts, recall notices.

II. SERVICE INFORMATION

Last date serviced _____

Service performed by _____

Was service on schedule? _____

Attach service records.

III. EVENT INFORMATION

Event result (death, injury, illness, malfunction) _____

Date of event _____

Specific injury incurred _____

_____

Date that medical personnel became aware of the event _____

Date reported to manufacturer _____

Was device used as labeled/intended? (attach copy of label) _____

Device operator when event occurred (name, title) _____

_____

Location of event _____

Other relevant devices in use at time of event _____

_____

_____

_____

_____

Brief event description (what happened, how was device involved). Attach expanded narrative if needed. _____

_____

_____

_____

_____

_____

_____

_____

_____

Witnesses to event (name, title, phone)

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

IV. PATIENT INFORMATION

Record for each patient involved. Use separate forms as necessary.

Name _____

Address _____

_____

Phone _____

Classification (inpatient, outpatient, visitor, employee) _____

Patient ID no. _____

Room number _____

Age _____ Sex _____ Weight _____

Attending physician _____

_____

Known allergies _____

Diagnosis before event _____

_____

Medical status before event (e.g., stable, critical, fair) _____

Was more than one patient involved? _____

If so, collect information for all patients.

V. INJURY ASSESSMENT

Time of discovery _____

Elapsed time from placement of device _____

Description of injury _____

_____

_____

Location of injury on patient (e.g., head) _____

Location of suspect device in relation to injury _____

Extent of injury at time of discovery

_____

_____

Were photos of injury taken? (if yes, attach to this form) _____

Patient treatment _____

_____

_____

Patient follow-up (current status)

_____

_____

VI. INCIDENT INVESTIGATION

Collect relevant data for each device involved in incident, including disposables. Use separate forms as necessary.

Date reported to risk management

_____

Date investigation initiated _____

Switch/control/indicator settings at time of incident (indicate whether typical—y or n) _____

_____

_____

_____

_____

_____

Relevant environmental conditions

_____

_____

Has device malfunctioned before?

_____

When? _____

Description of prior malfunction

_____

Was report filed? _____

Was corrective action taken or repair performed? (describe) _____

_____

_____

Positions and conditions of device, accessories, disposables _____

_____

_____

_____

_____

On a separate sheet, sketch positions relative to patient.

Who inspected the device following incident? _____

Did the device manufacturer witness the inspection? _____

Name of witness _____

_____

Types of tests performed (e.g., electrical) _____

Inspection findings (Did device fail? How? What components, attached devices, or subassemblies failed? Was the device used correctly?) Attach expanded narrative if needed.

_____

_____

_____

_____

_____

_____

_____

_____

_____

VII. INVESTIGATION CONCLUSIONS

Was the device the direct cause of the event? _____

How did the device cause or contribute to the event? _____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Immediate actions required

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Follow-up required

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____