Appendix R: Clinical Center Responsibilities for Medical Device Reporting

The FDA requires United States (US) "user facilities", which they define as "a US hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility", to report all serious injuries and deaths associated with a medical device to the FDA, MSCD manufacturer, or both. All US sites participating in Intermacs® are required to report serious injuries and deaths, where there is a reasonable possibility that the device may have caused or contributed to the event, according to 21 CFR 803.10 and summarized in the table below and 21 CRF 803.30. Refer to 21 CFR 803.32 for the information required in the medical device report (MDR) and 21 CFR 803.33 for MDR annual reporting requirements. More detailed information on MDRs is located at: http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

Summary of MDR Reporting Requirement Under 21 CFR 803.30

REPORTER	WHAT TO REPORT	WHERE	WHEN
Manufacturer	Deaths, Serious Injuries, Malfunction	FDA	Within *30 calendar days* of becoming aware
	Events that require remedial action to prevent an unreasonable risk of substantial harm	FDA	Within 5 working days of becoming aware
User Facility	*Deaths*	*FDA and Manufacturer*	*Within 10 working days*
	Serious Injury	*Manufacturer*	*Within 10 working days*
Voluntary	Any type of event	FDA	Any time