



## **Safety Recalls and Alerts Policy**

CIRACET receives medical equipment hazard notices and recalls from various sources, including directly from manufacturers and publications. The main source used by CIRACET for obtaining the best up-to-date information is MedWatch. MedWatch is the FDA Safety Information and Adverse Event Reporting Program that serves both healthcare professionals and the medical product-using public. They provide important and timely clinical information about safety issues involving medical products, including prescription and over-the-counter drugs, biologics, medical and radiation-emitting devices, and special nutritional products.

In the event of a Safety Recall CIRACET's engineers will verify if the equipment being recalled is on the inventory. If the equipment is in inventory a recall memorandum will be made available to the Plant Facilities Director.

MedWatch also allows [healthcare professionals](#) and [consumers](#) to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use. Reporting can be done [on line](#), by phone, or by submitting the MedWatch 3500 form by mail or fax. Reporting to the FDA or any other agency will be the Hospital's responsibility. CIRACET will provide any necessary information and will cooperate in any tasks related to a safety issue.

CIRACET also complies with the User Reporting Requirements of the Safe Medical Devices Act of 1990. CIRACET will report to the Plant Facilities Department and the Safety Committee of any patient incident related to the malfunction of a medical equipment. The Safety Committee or the person designated by the hospital will be responsible of reporting the incident to the FDA as required by the Safe Medical Devices Act of 1990.