Section 9 Subject 9.13 **Policy 9.13.11**	Clinical Policies General Procedures **Medical Device Recall, Alert, Safety Hazard Notification and Response**	04/01/90 -Originated 10/11/12 -Reviewed w/ changes 02/16/09 -Reviewed w/o changes 11/27/12 -Effective Risk Management - Author

Medical Device Recall, Alert, Safety Hazard Notification and Response

Definition

Medical Device: A medical device is a device used in the diagnosis, treatment, cure, mitigation, or prevention of a disease or physical condition. These may include electrical or mechanical equipment, biologics, tissue, blood products, drugs, food, or dietary supplements.

Recall / Alert / Safety Hazard Notice: A recall, alert, or safety hazard notice is sent by a manufacturer or the FDA and communicates a known or potential defect or unsafe condition of a medical device.

Policy

UTMB is committed to patient safety and responds accordingly to medical device recall notices as required by the FDA.

UTMB departments shall comply with the recommendations included in any recall, alert, or safety hazard notice provided by the FDA and/or product manufacturer. Compliance efforts, or an explanation of any differences between the manufacturer's recommendations and UTMB activities, shall be communicated via the ECRI Alerts Tracker system or routed to Risk Management.

Notification Process

Medical Device recalls and safety hazard notifications are received by and distributed to the appropriate department director (or designee) by Risk Management using the ECRI Alerts Tracker system. Recipients of ECRI alerts shall review the information provided, determine applicability, complete corrective action recommended by the manufacturer or the FDA, and document such efforts via the ECRI Alerts Tracker system in a timely manner.

Medical device recalls and safety hazard notices are also received by Risk Management via letter or e-mail delivery and are distributed electronically to the appropriate department director (or designee) for processing as described above.

Medical device recalls and safety hazard notices received by a department other than Risk Management shall be forwarded to Risk Management for processing.

A record of all recalls and safety hazard responses received will be maintained by Risk Management.

Patient Contact

Physicians should be considered the primary liaison in concert with Risk Management when circumstances require that a patient be contacted.