

UConn HEALTH

CLINICAL POLICY Medical Device Recall Notification

A. EFFECTIVE DATE :

April 20, 2021

B. PURPOSE :

To assure that medical devices are addressed in a timely manner after issuance of a recall notification.

C. POLICY :

This policy is in accordance with the Medical Device Amendments of 1976 of The Food, Drug and Cosmetics Act and subsequent Safe Medical Devices Act of 1990 (Act), requires the clinical engineering department to review and address the reported recall notifications as provided by the FDA and/or manufacturer.

D. SCOPE :

Medical devices that reside within JDH and UMG patient care areas.

E. DEFINITIONS :

ECRI Alerts Tracker System- A Web-based system to provide electronic distribution and electronic repository of Product Recalls, Field Corrections and Product Hazard Alerts.

F. MATERIAL(S) NEEDED :

NONE

G. PROCEDURE :

- 1) The Clinical Engineering Manager will serve as the Medical Device Recall Coordinator and will receive and address pertinent medical device recalls sent to the hospital via mail or email.
- 2) On a regular basis, the ECRI Alerts Tracker electronically distributes applicable hazard alert/product recalls to each user assigned to the particular area of responsibility. The following health center departments will address any alert/recalls that are assigned under their areas of responsibility. Each of these departments shall review the notifications in a timely manner to determine relevance to their areas of responsibility; and act accordingly to their respective policies/procedures for addressing recall notifications.

<u>Department</u>	<u>Product Responsibility</u>
Clinical Engineering	Medical Equipment, Non-Disposables
Clinical Laboratory	Laboratory Equipment, Blood Products
Purchasing/Materials Management	Disposables, Implants-Central Warehouse and medical/surgical supplies

Facilities Maintenance & Operations	Facilities-related products
Radiology	Area specific products
Operating Room	Area specific products
Cardiology/Respiratory	Area specific products
Research	Area specific products
Safety	
School of Medicine	Area specific products
School of Dental Medicine	Area specific products
Ambulatory Services	Area specific products
Pharmacy	Maintains a separate manual system

4) Any hospital department receiving a product recall, field correction, or hazard alert directly from a manufacturer or other outside source, will respond to the notification, if applicable, and forward the notification to the Clinical Engineering Manager (Hazard Alert/Product Recall Coordinator) as needed.

5) **URGENT, LIFE-THREATENING RECALLS OR HAZARD ALERT, NOTIFICATIONS** will be telephoned and emailed to relevant areas. The Hazard Alert/Product Recall Coordinator shall also be notified by the department first receiving the notification.

H. ATTACHMENTS :

NONE

I. REFERENCES :

Reporting Adverse Medical Device Incidents, Policy #11-032.

J. SEARCH WORDS :

NONE

K. ENFORCEMENT:

Violations of this policy or associated procedures may result in appropriate disciplinary measures in accordance with University By-Laws, General Rules of Conduct for All University Employees, applicable collective bargaining agreements, the University of Connecticut Student Code, other applicable University Policies, or as outlined in any procedures document related to this policy.

L. STAKEHOLDER APPROVALS :

On File

M. COMMITTEE APPROVALS :

NONE

N. FINAL APPROVAL :

- | | |
|---|---------------------------|
| 1. <u>Andrew Agwunobi, MD (Signed)</u>
Andrew Agwunobi, MD, MBA
UConn Health Chief Executive Officer | <u>04/28/2021</u>
Date |
| 2. <u>Anne Horbatuck (Signed)</u>
Anne D. Horbatuck, RN, BSN, MBA
Clinical Policy Committee Co-Chair | <u>04/28/2021</u>
Date |
| 3. <u>Scott Allen (Signed)</u>
Scott Allen, MD
Clinical Policy Committee Co-Chair | <u>04/27/2021</u>
Date |
| 4. <u>Caryl Ryan (Signed)</u>
Caryl Ryan, MS, BSN, RN
VP Quality and Patient Services & Chief Nursing Officer | <u>04/27/2021</u>
Date |

O. REVISION HISTORY :

Date Issued: 7/76
Date Revised: 1/86, 11/88, 12/88, 9/91, 8/09, 10/14, 5/18, 3/21
Date Reviewed: 11/94, 5/97, 2/00, 10/03, 05/06, 9/08, 09/12, 04/16