TITLE: Product Recall
Revised: 11/2017

I. Purpose.

The purpose of this policy is to define the process for product recalls, the responsible person(s) and the steps to be taken in the event of a Device and/or Product Failure/Recall.

II. Philosophy.

It is the policy of the Massachusetts General Hospital (MGH) to take appropriate action upon receipt of information of medical device and/or product related hazards. This action includes communicating internally identified issues as well as externally generated notices to the appropriate constituents. In addition to providing a safe care environment, the policy provides the opportunity to trend failures across the network and holds manufacturers accountable.

III. Scope.

This policy applies to all licensed entities of the MGH as applicable.

IV. Policy.

The MGH PNG Site Leader has the overall responsibility for the implementation of this Policy. The members of the MGH PNG and PHS Recall Coordinator (recallcoordinator@partners.org) assist the Site Leader in the dissemination of information and collection of affected products. Each MGH Department is responsible for maintaining an updated ***Product Notification Communication Plan***. This Plan should be located where it is easily retrievable by staff. Formal notifications of product/ device problems are normally directed to the Partners Supply Chain Management Department. All notices that are directed to a department other than Partners Supply Chain Management are to be forwarded to the Recall Coordinator at recallcoordinator@partners.org. The United States Food and Drug Administration requires that manufacturers inform them of all serious or potentially serious problems associated with medical devices. The FDA compiles this information and distributes it through the product recall Alert Center, a nonprofit service agency. The FDA also maintains a web site (MEDWATCH) with links to information about medical device alerts, notices, and recalls.

Upon receipt, external notification of product/device recall or Safety alert information is disseminated, as described in this policy, to departments for

appropriate action. Internal notices or information learned within the hospital regarding product/device problems may also be disseminated per this policy.

V. Product Recalls Notification (General)

A. Procedures and Responsibilities

The following procedures will be used to notify departments and to follow up on any product recalls or notifications from governmental agencies and manufacturers.

1. All notifications concerning a suspected product hazard are to be forwarded immediately to the Partners Materials Management Department Recall Coordinator. The PHS Recall Coordinator can be reached at recallcoordinator@partners.org
2. The PHS Recall Coordinator will disseminate the hazard alert, risk bulletin or information notice (see **Appendix A** for examples) to the MGH Product Notification Group (PNG)/Risk and appropriate MGH departments where the product may be available.

B. Par Level Supplies

1. The responsibility for searching and securing of supplies will reside with the ordering department. The Materials Management Department is responsible for searching and securing supplies from par level supply areas. Materials Management will need support in retrieving product from the other locations on a unit that the product may be held.
a. All identified products will be handled as indicated in the Alert Bulletin or Hazard instructions. If necessary, the Materials Management Department will replace the product with an acceptable substitute.

C. Disposing of Recalled Products

1. All recalled products awaiting disposition will be quarantined in a secure area and labeled as, “Do Not Use: Recalled Product.”
2. Recalled items will be removed from the premise as quickly as possible.
4. The Recall Coordinator will be notified of action taken.

V. Medical Device Recalls/Notifications (EXTERNAL)

A. Procedures and Responsibilities

The following procedures will be used to notify departments and to follow up on any medical device recalls/notifications from governmental agencies and manufacturers.

1. All notifications concerning a suspected medical device hazard will be forwarded immediately to the Partners Supply Chain Management Department Recall Coordinator. The Recall Coordinator can be reached at recallcoordinator@partners.org.
2. The PHS Recall Coordinator will disseminate the hazard alert, risk bulletin or information notice to the MGH Product Notification Group and appropriate departments where the devices may be in use.
3. The department(s) receiving the notification will ensure that all end users are informed as appropriate.
4. The Department PNG representative notifies the MGH Site Leader and PHS Recall Coordinator of the plan's completion.
5. The MGH Site Leader and the PHS Recall Coordinator maintain files on the activity and status of all recalls.
6. If the item is managed on the par level program by Materials Management, Materials Management will check the par level shelf locations in all par level department locations to determine if the affected product is or is not on hand. Materials Management will send a completed copy of any required forms to the vendor, MGH Site Leader, PHS Recall Coordinator on any items managed by Materials Management. If the item was ordered by the MGH Department directly, the Department PNG Representative will check to determine if the affected product is on hand and will close out and send a completed copy of any required forms to the vendor, MGH Site Leader and the PHS Recall Coordinator.

VI. Dealing with Medical Device and Product Hazards Identified Internally (INTERNAL)

A. Procedures and Responsibilities

The following outlines the policy and procedures for managing a potential product or medical device hazard that is identified by an employee or other internal source. This section is applicable when the discovery of a potential hazard is brought to the attention of the Product Notification Group by an internal source.

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1. Anyone suspecting a potential hazard with a product or device should sequester the product or device and contact the supervisor or a member of the Product Notification Group.
2. The MGH Site Leader will ensure that the responsible person:
retrieves and safely stores the product and any accompanying packing or labeling, using a bio-hazard bag if necessary. The responsible person should also submit an online safety report if applicable.
3. The MGH Site Leader and/or PNG representative, in consult with the PHS Recall Coordinator, will develop an MGH Action Plan.
4. The group will determine steps to minimize the hazard, including product removal, substitution, or use with instructions.
5. Based on the direction from the Product Notification Coordinator, the PHS Recall Coordinator will disseminate the hazard alert, risk bulletin or information notice to appropriate departments where the product or device may be in use.
6. Depending up the nature of the product/device failure and in consult with the Quality and Safety department, a MedSun report may be filed with the FDA.
7. The department(s) receiving the notification will ensure that all end users are informed as appropriate.
8. The PHS Recall Coordinator will inform individuals with responsibilities in other hospital areas as appropriate.
9. The department or other designee receiving the notice will implement the actions indicated in the notification.
10. The department or other designee is responsible for notifying the Recall Coordinator when all actions are completed.
11. The MGH Site Leader and Department PNG representative and the PHS Recall Coordinator maintain files on the activity and status of all recalls.

APPENDIX A
Recall Bulletin Templates

INFORMATIONAL ALERT- (enter product/device info)

(print on white paper)

Date:

Notice #:

Subject: (insert picture of product/device)

Issue:

Action Required:

For clinical questions please contact: (enter a clinical contact name and pager id#)

For stocking questions please contact: (enter Materials Management contact name and pager id#)

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Risk Bulletin- (enter product/device info)

Use with Caution

(print on yellow paper)

Date:

Notice #:

Subject: (insert picture of product/device)

Issue:

Action Required:

For clinical questions please contact: (enter a clinical contact name and pager id#)

For stocking questions please contact: (enter Materials Management contact name and pager id#)

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HAZARD ALERT- (enter product/device info)

(print on pink paper)

Date:

Notice #:

Subject: (insert picture of product/device)

Issue:

Action Required:

For clinical questions please contact: (enter a clinical contact name and pager id#)

For stocking questions please contact: (enter Materials Management contact name and pager id#)

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