Recall Communication: Medical Device Model Recall Notification Letter

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Center for Devices and Radiological Health
Company Recall Requirements

- The recalling company is responsible for promptly notifying each of its affected direct accounts (that is, distributors, contractors, customers) about a recall.

- A recall communication can be in the form of a press release, telephone call, telegram, mailgram, or a first class letter. It is highly recommended that the recalling firm discuss a recall letter with the FDA district office recall coordinator prior to issuing the notification.

www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ucm243982.htm

www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals/default.htm
What is the reason for the company’s notification?

- To provide details regarding the product recall
- To supply information to help users identify the product
- To minimize health consequences by providing instructions on what action(s) need to be taken

www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ucm243982.htm
Recall Notification

- First Class Letter should be conspicuously marked, preferably in bold red type, on the letter and the envelope: "URGENT Medical Device Recall."

- The letter and the envelope should be also marked "URGENT" for Class I and Class II recalls and, when appropriate, for Class III recalls.

- Telephone calls or other personal contacts should be confirmed by one of the above methods and/or documented in an appropriate manner.

www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals/default.htm
Company Name
Date (Month, Day, Year)

URGENT: MEDICAL DEVICE RECALL

<>PRODUCT NAME>

Customer Name
Device Name
Street Address
City, State, Zip Code

Dear Device Customer/Distributor,

The purpose of this letter is to advise you that Company Name is voluntarily recalling Product X (include the name, intended use, indication, and any additional identification) due to problems or defects described in the Product and Distribution Information section.

The following information (if available) should be included:
- Frequency of failures and complaints
- Events that resulted in the failure
- Reports of harm or death
- Information about similar devices

Reason for the Voluntary Recall:

The purpose of this letter is to advise you that Company Name is voluntarily recalling Product X (include the name, intended use, indication, and any additional identification) due to problems or defects described in the Product and Distribution Information section.

Note: It is important that the device be returned to the manufacturer for evaluation.

Risk to Health:

Describe how the device failure or problem will affect patients, health care providers, or other persons who are exposed to the device. The failure or problem may cause injuries, delay in diagnosis, or other delays in treatment or therapy, provide an explanation of why that is so.

Add the statement “How to recognize the device may fail.” Describe the methods of recognition of the device failure by the customer/user. Give an explanation (in lay terms) of how the failure occurs and how to recognize the issue.

Actions to be taken by the Customer/User:

Describe actions for safe handling of the recalled product (for example, discontinue use, keep the device in a safe place, etc.). State whether these actions are temporary or permanent and long-term, if applicable. When a long-term solution will be implemented. At a minimum, ensure that the following elements are included:
- Recommended treatment or actions for users to minimize risk of illness or injury
- Actions to be taken pending corrective or removal of the device
- Alternative products that can be used if applicable, and whether removal of the product may cause a shortage
- Specific instructions for sub-division and any associated recall
- Instructions for acknowledgment (FAX back, email, telephone, etc.)

Product and Distribution Information:

This table is not limited to the information listed below. Please insert additional information as applicable. Photocopies of the product are optional, but encouraged.

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Product Number</th>
<th>Lot/Serial</th>
<th>Manufacturing/Distribution</th>
<th>Expiration Date</th>
<th>Quantity</th>
</tr>
</thead>
</table>

Type of Action by the Company:

What is the firm doing to correct this issue? (for example, system updates, repair, and change in labeling). When will these corrective actions be taken by the company?

- Failure investigation
- Remedy
- Replacement
- Repair
- Instruction/withdrawal
Company Name
Date (Month, Day, Year)

URGENT: MEDICAL DEVICE RECALL

<Product Name>
Company Name
Date (Month, Day, Year)

URGENT: MEDICAL DEVICE RECALL

PRODUCT NAME

Customer Name
Device Name
Ship To Address
City, State, Zip Code

Dear Device Customer/Dealer,

The purpose of this letter is to advise you that Company Name is voluntarily recalling Product X (include the name, model, use definition, and any additional identification) due to the risk of injury to the patient or user. (Include the name and address of the manufacturer and their contact information).

If any serious injuries have occurred or could occur as a result of the device, add this sentence to the risk section: “Serious injuries or deaths have occurred or could occur because the device is defective in its design or manufacture.”

Reason for the Voluntary Recall:

Identify the product concerns/problems, whether actual or potential, in detail. Include the following information, if available:

- Frequency of failures and complaints (for example, “We are aware of [number] of product failures and [number] of complaints related to the problem.”)
- Adverse events (injuries, deaths)

Risk to Health:

Explain how the device failure or problem will affect patients, health care providers, or other persons who are exposed to the device. If the device failure can cause injury, delays in surgical procedure, or other delays in treatment or therapy, provide an explanation of why that is true.

Add the statement “How to recognize that the device may fail.” Describe the symptoms of the device failure by the customer/user. Give an explanation (in lay terms) of how the failure occurs and how to detect/recognize the issue.

Actions to be taken by the Customer/User:

Describe actions for safe handling of the recalled product. (For example, do not use the product, dispose of the product, etc.). State whether these actions are temporary or permanent and, if applicable, when a permanent solution will be implemented. At a minimum, ensure that the following elements are included:

- Recommended treatment or actions for patients/health care providers to minimize risk of illness or injury
- Actions to be taken pending corrective or removal of the device
- Substitute products that can be used if applicable, and whether removal of the product may cause a shortage
- Specific instructions for sub-tenant and any associated facilities (for example, in a device is also marketed under a different brand name and included as a component in a kit, the kit will need to be recalled, if applicable)
- Instructions for acknowledgment (e.g., email, telephone, etc.)

Product and Distribution Information:

This table is not limited to the information listed below. Please insert additional information as applicable. Photographs of the product are optional but encouraged.

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Product Number/Date Code</th>
<th>Expiration Date</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product X</td>
<td>Company Name</td>
<td>1234567890</td>
<td>2023-12-31</td>
<td>100</td>
</tr>
</tbody>
</table>

Type of Action by the Company:

What is the firm going to do (for example, system update, removal, and change in labeling)? When will these corrective actions be taken by the company?

- Failure Investigation
- Recall Plan

[Company Name] Date (Month, Day, Year)
Dear Device Customer/Distributor,

The purpose of this letter is to advise you that Company Name is voluntarily recalling Product X (include the name, intended use statement, and any additional identification detail not covered in the Product and Distribution Information section).

Note: If any serious injuries and/or deaths have occurred or could occur as a result of the failure of the device, add this sentence in bold font: “Serious injuries and/or deaths have occurred or could occur due to the failure of this product. We have reports of [number of] deaths and/or [number of] of serious injuries.”

Reason for the Voluntary Recall:

Identify the product concerns/problems, whether actual or potential, in detail (For example, what happens when the device fails). Include the following information, if available:

- Frequency of failures and complaints (for example, “We are aware of [number of] product failures and [number of] complaints related to the problem.”)
- Adverse events (that is, injuries, deaths)
Company Name
Date (Month, Day, Year)

URGENT: MEDICAL DEVICE RECALL

<PRODUCT NAME>

Customer Name
Device Name
Ship To Address
City, State, Zip Code

Dear Device Customer/Provider,

The purpose of this letter is to advise you that Company Name is voluntarily recalling Product X (include the name, intended use description, and any additional identification deemed not covered in the Product and Distribution Information section).

Note: If many serious injuries and/or deaths have occurred or could occur as a result of the failure of the device, add a sentence in bold font: “Serious injuries and/or deaths have occurred or could occur due to the failure of this product. We have reports of [number of injuries/deaths] and [number of serious injuries].”

Reason for the Voluntary Recall:

Identify the product concerns/problems, whether actual or potential, in detail. (For example, what happens when the device fails.) Include the following information, if available:

- Frequency of failures and complaints (for example, “We are aware of [number of] product failures and [number of complaints related to the problem].”)
- Adverse events (if any, include deaths, injuries).

Product and Distribution Information Table:

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Lot/Batch Number</th>
<th>Manufacturing/Distribution</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Type of Action by the Company:

What is the firm doing to correct this issue? (For example, system updates, removal, and change in labeling.) When will these corrective actions be taken by the company?

- [Failure investigation process/plan]
Recall Notification Footnotes

1. Recommended for Class I and II recalls. “Urgent” should be noted on both the letter and envelope as per 21 CFR 7.49(4)(b).

2. For radiation-emitting electronic products, a recall action is governed by 21 CFR 1004 – Repurchase, Repairs, or Replacement of Electronic Products – under which manufacturers are required to bring such products into conformity with applicable performance standards or correct any reported device defect at no charge to the user. Medical device recalls are governed by 21 CFR 806 – Reports of Corrections and Removals – which does not contain an equivalent requirement.
Company Name
Date (Month-Day-Year)

URGENT: MEDICAL DEVICE RECALL <PRODUCT NAME>

Customer Name
Device Name
Street Address
City, State, Zip Code

Dear [Device Customer/Distributor],

The purpose of this letter is to inform you that Company Name is voluntarily recalling Product X (include the name, model use statement, and any additional identification) due to the failure or defect described in the Product and Distribution Information section.

Note: If serious injuries and/or deaths have occurred or could occur as a result of the failure of the device, add this sentence in bold font: “Serious injuries or deaths have occurred or could occur due to the failure of this product.” We have reports of number of deaths and number of serious injuries.

Reason for the Voluntary Recall:

Identify the product concerns/problems, whether actual or potential. For example, what happens when the device fails. Include the following information, if available:
- Frequency of failures and complaints (for example, “We are aware of [number of] product failures and [number of] complaints related to the problem.”)
- Adverse events (e.g., injuries, deaths)

Risk to Health:

Explain how the device failure or problem will affect patients, health care providers, or other persons who are exposed to the device. Durable device failure can cause injuries, delays in medical procedures, or other delays in treatment or therapy, provide an explanation of why that is so.

Add the statement “How to recognize that the device may fail.” Describe the methods of recognition of the device failure by the customer/user. Give all explanation/lay terms of how the failure occurs and how to detect/recognize the issue.

Actions to be taken by the Customer/Use:

Describe actions for safe handling of the recalled product (e.g., discontinue use, dispose of the product, return the product, etc.). State whether these actions are temporary or long-term and, if applicable, when a long-term solution will be implemented. At a minimum, ensure that the following elements are included:
- Recommended treatment or actions for users to minimize risks of illness or injury
- Actions to be taken pending corrective or removal of the device
- Alternative products that can be used if applicable, and whether removal of the product may cause a shortage
- Specific instructions for sub-recall and any associated recalls (e.g., if a device is also marketed under a different brand name as a component in a kit that will also need to be recalled, if applicable)
- Instructions for acknowledgment (e.g., fax, phone, email, etc.)

Product and Distribution Information: This table is not limited to the information listed below, please insert additional information as applicable. Photographs of the product are optional, but encouraged.

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Lot/Batch Number</th>
<th>Expiration Date</th>
<th>Quantity</th>
</tr>
</thead>
</table>

Type of Action by the Company:

What is the firm doing to correct this issue? (e.g., software updates, repair, replacement, and change in labeling). When will these corrective actions be taken by the company?
- [Brief Action Information]
Risk to Health:

Explain how the device failure or problem will affect patients, health care providers, or other persons who are exposed to the device. If the device failure can cause injuries, delays in surgical procedures, or other delays in treatment or therapy, provide an explanation of why that is so.

Add the statement "How to recognize that the device may fail." Describe the methods of recognition of the device failure by the customer/user. Give an explanation (in lay terms) of how the failure occurs and how to detect/recognize the issue.

Actions to be taken by the Customer/User:

Describe actions for safe handling of the recalled product (for example: discontinue use, discard or correct the product, return the product, etc.) State whether these actions are temporary or long-term and, if applicable, when a long-term solution will be implemented. At a minimum, ensure that the following elements are included:

- Recommended treatment or actions for users to minimize risks of illness or injury
- Actions to be taken pending corrective or removal of the device
- Alternative products that can be used, if applicable, and whether removal of the product may cause a shortage
- Specific instructions for sub-recall and any associated recalls (for example, if a device is also marketed under a different brand name or is included as a component in a kit that will also need to be recalled, if applicable)
- Instructions for acknowledgement (FAX back, email, telephone, etc.).
Recall Notification Letter

Company Name

Date (Month, Day, Year)

URGENT: MEDICAL DEVICE RECALL

Customer Name
Device Name
Shipment Address
City, State, Zip Code

Dear [Device Customer/Recipient]:

The purpose of this letter is to advise you that Company Name is voluntarily recalling Product X (include the name, intended use, statement, and any additional identification) listed below:

Reason for the Voluntary Recall:

- Identify the product concerns/problems, whether actual or potential. (For example, what happens when the device fails). Include the following information, if available:
  - Frequency of failures and complaints (for example, "We are aware of [number] of product failures and [number] of complaints related to the problem.")
  - Adverse events (e.g., injuries, deaths)

Product and Distribution Information:

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Lot/Batch Number</th>
<th>Date Released</th>
<th>Expiration Date</th>
<th>Quantity</th>
</tr>
</thead>
</table>

Type of Action by the Company:

- What is the firm doing to correct this issue? (For example, system updates, repair, and change in labeling). When will these corrective actions be taken by the company?
  - Failure investigation

Risk to Health:

- Explain how the device failure or problem will affect patients, health-care providers, or other persons who are exposed to the device. (The device failure can cause injuries, delays in surgical procedures, or other delays in treatment or therapy, provide an explanation of why that is.
- Add the statement "How to recognize that the device may fail." Describe the methods of recognizing the device failure by the customer/user. Give an explanation (lay terms) of how the failure occurs and how to detect/recognize the issue.
- Actions to be taken by the customer/user:
  - Describes actions for safe handling of the recalled product. For example, stop discontinuing use, discard or clean the product, return the product, etc. State whether these actions are temporary or permanent and, if applicable, when a long-term solution will be implemented. At a minimum, ensure that the following steps are included:
    - Recommended treatment or actions for users to minimize risk of illness or injury
    - Actions to be taken pending corrective or removal or the device
    - Alternative products that can be used if applicable, and whether removal of the product may cause a shortage
    - Specific instructions for sub-lesion and any associated recalls (for example, if a device is also marketed under a different brand name and is included as a component in a kit that will also need to be recalled, if applicable)
    - Instructions for acknowledgment (fax back, email, phone, etc.)

Product and Distribution Information: This table is not limited to the information listed above; include additional information as applicable. Photographs of the product are optional but encouraged.
Recall Notification Letter – Product Distribution and Action by Company

Product and Distribution Information: This table is not limited to the information listed below; please insert additional information as applicable. Photographs of the product are optional, but encouraged.

<table>
<thead>
<tr>
<th>Product Names, Unique Device Identifier (if applicable)</th>
<th>Manufacturer’s Product Number/Catalog Number</th>
<th>Lot/Serial Number</th>
<th>Manufacturing/Distribution Dates</th>
<th>Expiration Date (MM/DD/YYYY)</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Type of Action by the Company:

What is the firm doing to correct this issue? – (for example, system updates, removal, and change in labeling). When will these corrective actions be taken by the company?

- Failure Investigation findings:
OTHER INFORMATION:
- Contact information for questions
- Attachments of Acknowledgement and Product Replacement Forms (separate sheets)

Authorized by:
Name (Print):

Signature:

Title:

Contact Information (Include Days/Hours Available (with Time Zone)) for calls (such as, Monday through Friday, 8:00 AM to 4:30 PM, Eastern Time). Add a toll-free number and a dedicated website address if they are available.

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA:
- (form available to fax or mail), or
- Call FDA 1-800-FDA-1088
OTHER INFORMATION:
- Contact information for questions
- Attachments of Acknowledgement and Product Replacement Forms (separate sheets)

Authorized by:
Name: (Print)

Signature:

Title:

Contact Information: Include Days/Hours Available (with Time Zone) for calls (such as, Monday through Friday, 8:00 AM to 4:30 PM, Eastern Time). Add a toll-free number and a dedicated website address if they are available.

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA:
- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or
- Call FDA 1-800-FDA-1088
Recall Notification Format

- The format, content, and extent of the notification should be commensurate with the recall hazard and strategy.
MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form
Responsibilities Required

Customer Information:
- Name
- Street Address
- City, State, Zip Code

PRODUCT NAME

I have read and understand the recall instructions provided in the attachment letter. Yes / No

Any adverse events associated with the recalled product? Yes / No

If yes, please explain:

Was this device implanted? Yes / No

Affected Product Information: Include information that is applicable for affected products:

<table>
<thead>
<tr>
<th>Product/Brand Name</th>
<th>Manufacturer's Product Number/Catalog Number</th>
<th>Quantity in Inventory</th>
<th>Quantity Recalled</th>
<th>Quantity Destroyed/Returned</th>
</tr>
</thead>
</table>

Return Request Box:
Please provide any additional information if applicable.

Distributor:
I have checked my records and have quarantined inventory consisting of ___ units, cases, etc.

I have contacted and notified my customers that were shipped or may have been shipped this product by [date and method of notification].

Affected is a list of customers who received may have received this product. Please notify my customers.

Question(s): (When applicable)

Signature of Recipient:

Name/Title:

Telephone:

Mail Address:

PLEASE FAX COMPLETED RESPONSE FORM TO: Tel. #: ___, ATTN: ___
OR MAIL TO: [NAME AND ADDRESS]
Inappropriate Information in a Recall Notification

- Qualification data
- Promotional materials
- Any other statement that may detract from the message
Notification Follow-up

- When necessary, additional communication should be sent to customers who fail to acknowledge receiving the initial notice.
Consignee/Distributor Responsibilities

- Upon receipt of a recall notification, follow the instructions set forth by the recalling firm.
- When necessary, extend the recall to its customers in accordance with the instructions provided by the firm.
Conclusion

- Notification letters must provide clear details regarding the issue and the health risk to the users.
- Information identifying affected products must be easy to find.
- Actions to be taken by the users should be bulleted or numbered to clearly articulate the requirements to minimize risk or impact of affected product.
- Notification should be sectioned to allow the user to quickly see the information needed to react to the recall requirements.
Thank You

- If you have further questions regarding reporting requirements, contact:
  Your local FDA District Recall Coordinator at

CDRH’s Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at
1-800-638-2041, 301-796-7100 or
dsmica@fda.hhs.gov
Thank You

- If you have further questions regarding reporting requirements, contact:
  
  Your local FDA District Recall Coordinator at
  

  CDRH’s Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at
  
  1-800-638-2041, 301-796-7100 or
dsmica@fda.hhs.gov