Recall Communication: Medical Device Model Press Release

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Center for Devices and Radiological Health
What is a Recall Press Release?

- A Form of Public Warning
  - For urgent situations
  - Brief and to the point
  - Issued promptly

When is a Press Release for a device recall recommended?

- When products pose a significant health hazard (Class I Recalls and some Class II Recalls)
- When other forms of notification to consignees may be inadequate (e.g., devices sold directly to consumers)
It is a policy that press releases are issued for all Class I medical device recalls unless it will not be helpful to the public. For example:

- When initial consultation between patients and their physicians is essential
- There is inadequate information to convey risk and appropriate actions
- When product is limited to a small number of users that are easily identified and reached through targeted contact

www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm177312.htm
How can FDA support you in preparing your Press Release?

- Consult your local District Recall Coordinator before issuance whenever possible.
- Consumers may benefit from the clarity of a joint press release by FDA and your firm.

How can FDA support you in preparing your Press Release?

For those recalls where FDA believes a Press Release is warranted, the Agency will issue a Press Release if the firm has failed to do so, or if the firm-initiated press release is not adequate.

SEC. 705. [21 USC §375] Publicity
(b) The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger or gross deception of the consumer.

www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm
How is the information in the Press Release disseminated?

- The FDA Medical Device Recalls webpage
  [www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/default.htm](http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/default.htm)

- General news media, either national or local as appropriate

- Specialized news media, e.g., professional or trade press.
  [www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals/default.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals/default.htm)
## Medical Device Model Press Release

**Company Name** Issues Nationwide Recall of Product(s) Name(s)

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<thead>
<tr>
<th>FOR IMMEDIATE RELEASE: DATE</th>
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<tr>
<td>Company Address</td>
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### Purpose of the Press Release:

On (date) Company Name is initiating a nationwide recall of quantity and name of product(s). The product(s) have been found to describe problem, which has/potentially could result in describe public health risk. State if there is a related recall.

Consumers who have product(s) should stop using/return/replace/throw away/contact their doctor, etc.

Product(s) was manufactured from date to date and distributed from date to date.

The recall includes the following styles/models/UDI/ID numbers, (etc.) and quantity.

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Product(s) can be identified by provide additional details about how product(s) can be identified.

The firm voluntarily recalled the product(s) after becoming aware of (fill in). FDA has been notified of this action.

Brief explanation of what is known about the problem. Provide number, type and status of any injuries that have been CONFIRMED to date (For example, “No injuries have been reported to date.”).

Company is notifying its distributors and customers by describe method and is arranging for return/replacement/retrofit, etc. of all recalled product(s).

Product(s) was distributed to describe type of outlets, states/areas (Define area).

Consumers with questions may contact the company at 1-800-xxx-xxxx between the hours of x and x (include time zone) and email if 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](http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm) (form available to fax or mail), or
- **Call** FDA 1-800-FDA-1088
Press Release:  Header

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Press Release: Contact Information

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Do not include in Press Release

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

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=810.15
Conclusion

- Press releases must provide clear and concise information concerning the recall health risk to the users.
- Issue your press release promptly
- Contact your District Office with your draft press release to discuss content.
Helpful Links

- Medical Model Press Release;
  www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129289.htm

- ORA District and Headquarters Recall Coordinators;
  www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm

- Recalls, Corrections and Removals (Devices);
  www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals/default.htm

- Title 21 of the Code of Federal Regulations; Part 7 Enforcement Policy (21CFR 7) and Part 806 (21CFR 806),
Helpful Links

- Regulatory Procedures Manual (RPM), Chapter 7 Recall Procedures;
  www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm177312.htm

- Guidance for Industry: Product Recalls, Including Removals and Corrections;
  www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm

- Compliance Activities;
  www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/default.htm
Thank You

If you have further questions regarding reporting requirements, contact:
Your local FDA District Recall Coordinator at
www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm

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