What is a Medical Device Recall?

When a company learns that there is a problem with one of their medical devices, it proposes a **correction** or a **removal** depending on where the action takes place.

- **Correction** - Addresses a problem with a medical device in the place where it is used or sold.
- **Removal -** Addresses a problem with a medical device by removing it from where it is used or sold.

FDA uses the term “recall” when a manufacturer takes a correction or removal action to address a problem with a medical device that violates FDA law. Recalls occur when a medical device is defective, when it could be a risk to health, or when it is both defective and a risk to health.

A medical device recall does not always mean that you must stop using the product or return it to the company. A recall sometimes means that the medical device needs to be checked, adjusted, or fixed. If an implanted device (for example, an artificial hip) is recalled, it does not always have to be explanted from patients. When an implanted device has the potential to fail unexpectedly, companies often tell doctors to contact their patients to discuss the risk of removing the device compared to the risk of leaving it in place.

Examples of the types of actions that may be considered recalls:

- Inspecting the device for problems
- Repairing the device
- Adjusting settings on the device
- Re-labeling the device
- Destroying device
- Notifying patients of a problem
- Monitoring patients for health issues

Sometimes a company may be aware that there is a problem with a group of products, but it cannot predict which individual devices will be affected. To appropriately address the concern, the company may recall an entire lot, model, or product line.

Who recalls medical devices?

In most cases, a company (manufacturer, distributor, or other responsible party) recalls a medical device on its own (voluntarily). When a company learns that it has a product that violates FDA law, it does two things:

- Initiates a recall (through correction or removal)
- Notifies the FDA.

Legally, the FDA can require a company to recall a device. This could happen if a company refuses to recall a device that is associated with significant health problems or death. However, in practice, the FDA has rarely needed to require a medical device recall.

What does the FDA Do about Medical Device Recalls?

When the FDA learns of a company's correction or removal action, it reviews the strategy the company proposes to address the problem, assesses the health hazard presented by the product, determines if the problem violates FDA law, potential violations of FDA requirements, and if appropriate assigns the recall a classification (I, II, or III) to indicate the relative degree of risk.

> **Class I:** A situation where there is a reasonable chance that a product will cause serious health problems or death.
>
> **Class II:** A situation where a product may cause a temporary or reversible health problem or where there is a slight chance that it will cause serious health problems or death.
>
> **Class III:** A situation where a product is not likely to cause any health problem or injury.

Once classified, the FDA monitors the recall to ensure that the recall strategy has been effective. Only after the FDA is assured that a product no longer violates the law and no longer presents a health hazard, does the FDA terminate the recall.

How does the FDA Notify the Public about Medical Device Recalls?

When a company initiates a correction or removal action, the FDA posts information about the action in the Medical Device Recall Database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm).

The FDA updates the Medical Device Recall Database after it classifies the recall and again after it terminates the recall.

In addition, the FDA may post company press releases or other public notices about recalls, market withdrawals, and safety alerts (/recalls-market-withdrawals-safety-alerts) that may potentially present significant risks to consumers or users of the product.

After a recall has been classified, the FDA notifies the public in the weekly Enforcement Report (/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports). In addition, the FDA posts consumer information about Class I and some Class II and III recalls (/medical-device-recalls) in order to ensure that patients are aware of the seriousness of the potential health hazard posed by exposure to the product.

Additional Information

- Device Advice: Recalls, Corrections and Removals (Devices) (/recalls-corrections-and-removals-medical-devices)
- Medical Device Recall Database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm)
- FDA Enforcement Reports (/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports)