The International Medical Devices Database (IMDD) Variable Descriptions

Country (country): Country of event

Date (date): Date associated to the record identified as such in the original data source.

Device Class (risk_class): A risk based classification system for all medical devices. There may be differences between countries. The U.S. FDA classifies devices using the following values:

1 = Class I (low to moderate risk)

2 = Class II (moderate to high risk)

3 = Class III (high risk)

U = Unclassified

N = Not classified

F = HDE (Humanitarian Device Exemption)

Event Date Posted (date_posted): Date when the information related to the event was posted.

Event Initiated Date (date_initiated_by_firm): Date that the firm first began notifying the public or their consignees of the recall.

Event Risk Class (action_classification): A numerical designation assigned by local authorities to a particular event that indicates the relative degree of health hazard. Not all countries classify events by degree of hazard. There may be differences between the class systems, if they exist.

The most commonly used one includes a numerical designation (I, II, or III):

Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Event Status (status): Reports about the status of an event. In the case of the FDA a recall can be in progress (on-going), completed, terminated or pending.

Event Terminated Date (date_terminated): Date that FDA determined recall actions were completed and terminated the recall.

Event Type (type): Reports about the type of event taken place. The type of events reported are Recall, Safety Alert, and Field Safety Notice.

Recall: A correction or removal action taken by a manufacturer to address a problem with a medical device. 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 a patient 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.

Safety Alert: Alerts provide important information and recommendations about products. Even though an alert has been issued, it does not necessarily mean a product is considered to be unsafe. Safety Alerts, addressed to health workers and users, may include recalls. They can be written by manufacturers, but also by health officials.

Field Safety Notice: Field safety notices are communications sent out by medical device manufacturers or their representatives in relation to actions that they may be taking in relation to their product that is on the market. These are mainly for health workers, but also for users. They can include recalls and alerts.

Implanted Device (implanted): An indicator (YES/NO) that the device is placed into a surgically or naturally formed cavity of the human body intended to remain implanted for 30 days or more. It could also be determined by the health authorities from a specific country.

Local Authorities Determined Cause (determined_cause): Local authorities determined general type of event cause. In the case of the FDA, recall cause determinations are subject to modification up to the point of termination of the recall.

Manufacturer Name (name): Name of manufacturer of medical device

Parent Company of Manufacturer (parent_company): The parent company of the manufacturer

Product Classification (classification): The field identifies broad categories of medical specialties that would use specific devices, such as cardiology and orthopedics. It comes from the U.S. FDA Device Classification by Review Panel and was extended to other countries when needed to facilitate navigation.

Quantity in Commerce (quantity_in_commerce): The amount of defective products subject to a recall, safety alert or field safety notice.