A **medical device incident (MDI)** is an incident related to a failure of a medical device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use that has led to the death or a serious deterioration in the state of health of a patient, user, or other person, or could do so were it to recur.

AND

Is reported in Provincial Safety Management System (PSMS) under the icon labelled "Medical Device Incident"

Health Canada implemented mandatory reporting for Medical Device Incidents for all Canadian Hospitals in December 2019.

Types of Medical Devices Included

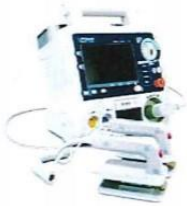
The term **medical device** covers a wide range of health and/or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition.

Medical devices are classified into **Class I** (lowest risk) to **Class IV** (highest risk). Examples are:

- Class I – hospital beds, wheelchairs, leg prostheses
- Class II – infusion sets, syringes, tracheostomy tubes, urethral catheters
- Class III – infusion pumps, anesthesia gas machines, intrauterine devices
- Class IV – pacemakers, defibrillators, breast implants, bone grafts

All classes of medical devices are included in mandatory reporting by hospitals.

Class I (Hospital bed)



Class IV (Defibrillator)

Source: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-document-guidance-risk-based-classification-system-non-vitro-diagnostic.html

Prepared by: Quality, Risk and Patient Safety Division
April 2021