MEDICAL DEVICE INCIDENTS

A **medical device incident (MDI)** refers to any incident related to a failure of a medical device or a deterioration in its effectiveness, or any inadequacy in its labelling, or in its directive for use. All MDIs are reported in the **Provincial Safety Management System (PSMS)** under the icon labelled '*Medical Device Incident*.'

WHAT IS A MANDATORY REPORTABLE MDI?

Any MDI that has led to **the death or a serious deterioration in the state of health** of a patient, client, resident, user, or other person, or could do so were it to recur **must** be reported to Health Canada. Mandatory reporting is based on criteria established for all Canadian hospitals by Health Canada in December 2019. This is also referred to as **Vanessa's Law**.

HOW ARE MANDATORY REPORTS SENT TO HEALTH CANADA?

MDIs are reviewed for completion and accuracy by Quality Patient Safety Consultants (QPSCs) and are sent to Health Canada automatically through PSMS.

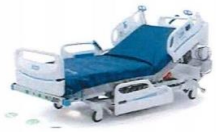
WHAT TYPES OF MEDICAL DEVICES ARE INCLUDED IN MDI REPORTING?

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.

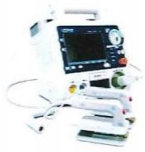
Medical devices are classified into **Class I** (lowest risk) to **Class IV** (highest risk). Examples are:

- 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)