6,334 reports of injury in 10 years

10 devices tied to the most reports involving injury (2008-2018)

- **896** Pacemakers (leads)
- **1918** Insulin infusion pumps
- **929** Hip prosthesis (acetabular cup)
- **922** Implantable ports or catheters
- **296** Hip prosthesis (metal head)
- **295** Implants for female incontinence (TVTs and Slings)
- **213** Over the counter blood glucose tests
- **220** Synthetic surgical mesh
- **284** Other infusion pumps (not insulin)
- **361** Intravenous infusion filters

Source: Health Canada & ICIJ

CBC NEWS
The government of Canada agrees that more can be done to further strengthen the oversight of medical devices and to be more open and transparent with Canadians about Health Canada’s regulatory activities.

The Honourable Ginette Petitpas Taylor  
Nov. 29, 2018
What is the secret of the Dalkon Shield’s high degree of contraceptive effectiveness? The answer lies in its ingenious design.

Prior to 1964 nobody had scientifically measured the size of the uterine cavity. Davis and Israel accomplished this by injecting silicone rubber compound into excised parous premenopausal uteri. From the molds which they obtained, they prepared permanent impressions in plaster of paris. Using these impressions, they measured the transverse dimensions of each uterine cavity at two points: 1 cm. from the fundus (transfundal superior), and 2 cm. from the fundus (transfundal inferior). They plotted these measurements on a graph to determine distributions of uterine cavity sizes. The Shield was designed to conform to the average of these dimensions, making it the only IUD which is truly “anatomically engineered” for optimum uterine placement, fit, tolerance, and retention.
TIMELINE
A VERY BRIEF HISTORY OF DEVICE REGULATION

1954
First Legislation
Medical device legislation including labelling, safety, effectiveness and recall requirements first introduced in Canada.

1975
Premarket Begins
Following public outcry and regulatory evaluation, the Regulations were updated to include premarket review oversight on a few select categories of medical devices.

1998
Licensing Begins
Following the 1992 report titled “Direction for Change” carried out by the Medical Devices Review Committee, the modern Regulations were born.

2019
Action Plan
HC’s Action Plan on medical devices was published in December of 2018. Today, the medical devices program is working to improve premarket and postmarket regulatory tools.
Food and Drugs Act

R.S.C., 1985, c. F-27

Current to June 21, 2019

Last amended on June 21, 2019
As a general concept, activities in which an individual, organization or government is involved can expose those or other stakeholders to hazards which can cause loss of or damage to something they value. Risk management is a complex subject because each stakeholder places a different value on the probability of harm occurring and its severity.

Implantable Cardiac Defibrillator (ICD)

- Subclavian
- Right Atrium
- Pacemaker Leads
- Heart
- Right Ventricle
Classification Rules for Medical Devices

PART 1
Medical Devices other than in Vitro Diagnostic Devices

Invasive Devices

Rule 1:
(1) Subject to subrules (2) and (3), all surgically invasive devices are classified as Class III.
(2) A surgically invasive device that is intended to diagnose, monitor, control or correct a defect of the central cardiovascular system or the central nervous system or of a fetus in utero is classified in Class IV.
(3) A surgically invasive device that is intended to be absorbed by the body, or that is normally intended to remain in the body for at least 30 consecutive days, is classified as Class III.

Rule 2:
(1) Subject to subrules (2) to (4), all invasive devices that penetrate the body through a body orifice or that come into contact with the cornea of the eye are classified as Class III.
(2) A device described in subrule (1) that is intended to be placed in the oral or nasal cavities as far as the pharynx or in the ear canal up to the ear drum is classified as Class I.
(3) A device described in subrule (1) that is normally intended to remain in the body or in contact with the surface of the eye for at least 30 consecutive days is classified as Class III.
(4) A device described in subrule (1) that is intended to be represented as preventing the transmission of infectious agents during sexual activities or reducing the risk thereof is classified as Class III.

Rule 3:
Despite rules 1 and 2:
(a) all denture materials and orthodontic appliances, and their accessories, are classified as Class IIa;
(b) all surgical or dental instruments are classified as Class I; and
(c) all latex condoms are classified as Class IIa.

PART II
Instruments médicaux autres que les instruments diagnostiques in vitro

Instruments effectifs

Rule 1:
(1) Sous réserve des paragraphes (2) et (3), les instruments effectifs chirurgicaux sont classés dans la classe IIa.
(2) Ils sont classés dans la classe IV s’ils sont destinés à diagnostiquer, surveiller, contrôler ou corrigier une défaut du système cardiovasculaire central ou du système nerveux central ou d’un fœtus en utero.
(3) Ils sont classés dans la classe III s’ils sont habituellement destinés à demeurer dans le corps pendant au moins 30 jours consécutifs ou s’ils sont absorbés par l’œil.

Rule 2:
(1) Sous réserve des paragraphes (2) à (4), les instruments effectifs qui pénètrent dans le corps par un de ses orifices ou qui entrent en contact avec la surface de l’œil sont classés dans la classe IIa.
(2) Ils sont classés dans la classe I s’ils sont destinés à être placés dans les cavités buccales ou nasales jusqu’au pharynx ou dans le canal auditif jusqu’au tympan.
(3) Ils sont classés dans la classe III s’ils sont habituellement destinés à demeurer dans le corps ou en contact avec la surface de l’œil pendant au moins 30 jours consécutifs.
(4) Ils sont classés dans la classe III s’ils sont destinés à être présents comme permettant de réduire la transmission d’agents infectieux dans le cadre d’activités sexuelles.

Rule 3:
Malgré les règles 1 et 2 :
(a) les produits dentaires et les appareils orthodontiques, ainsi que leurs accessoires, sont classés dans la classe IIa;
(b) les instruments chirurgicaux ou dentaires sont classés dans la classe I ;
(c) les condoms en latex sont classés dans la classe IIa.
Invasive Devices

Rule 1:

(1) Subject to subrules (2) and (3), all surgically invasive devices are classified as Class II.

(2) A surgically invasive device that is intended to diagnose, monitor, control or correct a defect of the central cardiovascular system or the central nervous system or of a fetus in utero is classified as Class IV.
Primary Risk Factors for Non-IVDD Devices

- **Transient**
- **Duration of Contact**
- **Permanent**

- **Non-Invasive**
- **Invasiveness**
- **Central Cardiovascular/Neural Tissue**

- **Low**
- **Potential for Transmission of Infectious Agents**
- **High**

- **Benign**
- **Energy Exposure**
- **Hazardous**
Special Rules

Rule 6:
A near patient IVDD is classified as Class III.
Primary Risk Factors for IVDD Devices

- Testing Laboratory
- One of Several Factors Considered
- Non-Transmissible & Treatable
- Low Impact

- Expertise of Intended User
- Importance of Information to Diagnosis
- The Nature of the Disease
- Impact of Result to Individual or Public

- General Public
- Sole Determinant
- Highly Transmissible & Deadly
- High Impact
The Regulations Affect Several Stakeholders

- Manufacturers are Canadian or international companies with legal control over a device.
- Importers are Canadian-based companies responsible for bringing devices into Canada.
- Distributors are companies with a Canadian presence that sell devices in Canada.
## Registration/Authorization Obligations

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<th>Class IV</th>
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- ✔️: Device Registration Required
- ☐: Company Registration Required
Documents Required for Licensing

1. Application Form
   - Government document used to register a medical device with Health Canada

2. Labelling
   - Package labelling, manuals, promotional material etc. used to represent a device

3. Quality Certification
   - Manufacturer has established a compliant quality management system

4. Regulatory Dossier
   - Package of information to establish the safety and effectiveness of a medical device
What is in a Regulatory Dossier?
Routes of Access

Investigational Testing Authorization
Part 3 of the regulations will allow for the investigational testing of medical devices in Canada which do not yet meet the safety and effectiveness requirements listed in Sections 10 to 20 of the Regulations.

Special Access
The Special Access Programme (SAP) considers requests from Health Care Professionals (HCP) for access to unlicensed medical devices for emergency use, or if conventional therapies have failed, are unavailable or are unsuitable. Additionally, the SAP grants authorizations for custom-made medical devices required for unique patient circumstances.
Please access or e-Learning tool to learn more:


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