COLLEGE OF DENTURISTS OF ONTARIO

Medical Devices and Health Canada Licensure: Information Sheet

Purpose

The College's mandate is to protect the public by ensuring Registered Denturists provide safe, ethical and competent denturism care and service. The opening up of the global marketplace and the development of novel technologies have provided Registered Denturists with the opportunity to source novel products, devices and materials manufactured both in and outside of Canada.

While the College's goal is not to interrupt innovation in the marketplace, it does have as its primary responsibilities the protection of public safety and compliance of Registered Denturists with existing regulations for medical devices. This practice advisory is intended to provide information on navigating the use, sale and licensure of medical devices in Canada.

Medical Devices and Types of Licences

Medical devices are used in the diagnosis, treatment, mitigation or prevention of a medical condition. They can include a variety of devices that Denturists may encounter such as dentures, bridges, crowns, resins, denture coatings, filling materials, prosthodontic appliances, artificial teeth, denture repair kits, and materials used in the fabrication of dentures.

Health Canada is the government agency that licenses medical devices under the Therapeutic Products Directorate. All medical devices must be approved by Health Canada. Although many medical devices may be cross licensed in the United States by the FDA, medical devices must be licensed by Health Canada in order to be approved for its use and sale in Canada. FDA approval does not imply approval by Health Canada.

There are two types of licenses issued by Health Canada:

1. **Medical Device Licence** – licence for the medical device itself
2. **Medical Device Establishment Licence** – licence for the establishment (company) that manufactures a medical device.

Medical devices are categorized as Class I, II, III, or IV based on the risks associated with their use, including the degree of invasiveness, duration of contact with the patient, energy transmission hazard, and consequences of device malfunction or failure.

Medical Device Classification System			
Device Class	**Risk**	**Examples**	**Licence Requirements**
Class I	Lowest	Cotton balls, cotton swabs, oral/tongue depressor, probes	Manufacturers and/or distributors must hold a Medical Device Establishment Licence
Class II	Low	Dentures, denture resins, resins for denture relining/repairing/rebasing, bridges, crowns, denture coatings, prosthodontic appliances, artificial teeth, denture repair kits, adhesive brackets and conditioners, and materials used in the fabrication of dentures	Medical Device Licence required for each Class II, III and IV device
Class III	Moderate	Tooth shade resin, tooth shade materials, varnish, filling material, resin coating, tooth bonding resin, implants	
Class IV	High	Defibrillators	

Quick Facts & Requirements

- Most medical devices Denturists encounter will be Class II or higher
- Class II devices or higher must have Health Canada's approval in the form of a Medical Device Licence
- Denturists must ensure that every medical device or material used in denture fabrication is approved by Health Canada
- For Class I devices, the manufacturer or the importer holds a Medical Device Establishment Licence.
- Denturists can search for active medical device licenses before purchasing or using any medical devices on Health Canada's website. For Class II, III and IV licences - Medical Devices Active Licence website. For establishment licences – Medical Device Establishment Licence website.
- Denturists can refer to Health Canada's guidance document to quickly determine what class a device falls under – Keyword Index to Assist Manufacturers in Verifying the Class of Medical Devices
- Sale or use of prohibited medical devices or materials not licenced by Health Canada is in breach of the *Medical Devices Regulations* and may be an act of Professional Misconduct for Registered Denturists