



CANADIAN DENTAL ASSOCIATION
L'ASSOCIATION DENTAIRE CANADIENNE

Guidance Document for Dentists Providing Human Allogeneic Transplants

Based on
*Guidance Document for Cell, Tissue and Organ Establishments:
Safety of Human Cells, Tissues and Organs for Transplantation*

Adopted April 6, 2009 By
Health Products and Food Branch
Health Canada

Prepared by the
Committee on Clinical and Scientific Affairs
© Canadian Dental Association 2010

**Canadian Dental Association
Guidance Document for Dentists
Providing Human Allogeneic Transplants**

The information in this Canadian Dental Association (CDA) document is to clarify the responsibilities of dentists who provide human allogeneic transplants or allografts to their patients with respect to Health Canada regulations.

Introduction

Many dentists routinely use a wide range of transplant products during surgeries, including autograft, allograft, xenograft and alloplastic products (see table below).

Table 1: Grafts Used in Dentistry	
Graft type	Source of graft material
Autograft	Same individual who is receiving the graft
Allograft	A different individual
Xenograft	A different species such as a pig or a cow
Alloplastic graft	Synthetic material

In April 2009, the Health Products and Food Branch of Health Canada adopted a document titled *Guidance Document for Cell, Tissue and Organ Establishments - Safety of Human Cells, Tissues and Organs for Transplantation* (http://www.hc-sc.gc.ca/dhp-mps/brgtherap/reg-init/cell/cto_gd_ld-eng.php) based on regulations for establishments such as dental offices involved in the transplantation of human cells, tissues and organs (CTOs).

In contrast to autografts and allografts, xenograft and alloplastic graft products are classified by Health Canada as medical devices rather than CTOs and are regulated under the *Medical Devices Regulations* (please refer to the *CDA Guidance Document Pertaining to Devices for Use in Dental Health Care*).

Background

The Health Canada document *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* (“CTO Regulations”) is an annex of the *Food and Drugs Act* and is found at: <http://laws.justice.gc.ca/eng/SOR-2007-118/page-1.html>.

The CTO Regulations are administered through the Health Products and Food Branch of Health Canada to minimize health risk factors to Canadians, and to maximize the safety provided by the regulatory system for health products and food.

The bulk of the CTO Regulations pertain to the processing of CTOs by source establishments as well as establishments that import and distribute, and include donor

testing, screening and assessment, retrieval, testing and measurements, preparation for use in transplantation, preservation, quarantine, banking, packaging and labelling. Only allogeneic organs and minimally manipulated cells and tissue for homologous use are regulated under these regulations.

Rationale for Regulations

Because the field of CTO transplantation changes as the science evolves, Health Canada has chosen to base the regulatory framework on national standards. The purpose of this regulatory framework is to minimize the potential health risks to Canadian recipients of human CTOs.

The CTO Regulations are relevant to dentists because they apply to all individuals and establishments in Canada that handle, process, distribute or import human organs and *minimally manipulated cells and tissues for homologous use in transplantation in another individual*. For example, a demineralized bone product combined only with a sterilizing, preserving or storage agent is considered minimally manipulated and therefore regulated under the CTO Regulations.

Definition of “Minimally Manipulated” Cells and Tissue
“Minimally manipulated” means (a) in respect of a structural tissue, that the processing does not alter the original characteristics that are relevant to its claimed utility for reconstruction, repair or replacement; and (b) in respect of cells and nonstructural tissue, that the processing does not alter the biological characteristics that are relevant to their claimed utility.

However, tissue products that are more than minimally manipulated and tissues for non-homologous use continue to be regulated under the *Medical Device Regulations*. For example, demineralized bone that is combined with a component other than a sterilizing, preserving or storage agent is considered a medical device. Therefore, the addition of a handling component such as calcium carbonate or gelatin is considered more than minimal manipulation and results in the product being regulated as a medical device.

Manufacturers that produce these tissue-based medical devices require a Canadian medical device licence to import or sell the device in Canada. A person, other than the manufacturer, who imports or sells the device in Canada, would require an Establishment Licence from Health Canada.

It is not a dentist’s responsibility to determine how to classify the tissue products, but rather, it is up to the manufacturer and importer to ensure that they are in compliance with appropriate regulations.

Establishments Affected by Regulations

Under the interpretation section of the guidelines, an “establishment” means a person, a partnership or an unincorporated entity, or a part of any of them, that carries out any of

the following activities in respect of cells, tissues or organs: a) importation; b) processing; c) distribution; d) transplantation. Thus **a dental office providing allografts is considered to be a transplant establishment.**

Table 2: Establishments, Activities and Registration Requirements		
Establishment	Activity relating to cells, tissues, or organs	Health Canada registration required?
Source / Manufacturer	Processing	Yes
Dental Supplier	Importation and Distribution	Yes
Dentist / Dental Office	Transplantation	No

Most of the CTO Regulations pertain to source establishments both in and outside Canada, establishments that import into Canada (other than transplant establishments that don't further distribute) and establishments that distribute CTOs within Canada. The CTO Regulations require establishments, other than transplant establishments, to register.

The CTO Regulations require establishments that distribute CTOs for transplantation to ensure that the *donor identification code* is on both the interior label and package insert. In addition, the source establishment must also provide its *Health Canada registration number* on the package insert and exterior label.

Finally, Health Canada may request, in writing, relevant information from any establishment to demonstrate that the activities it carries out are in compliance with the CTO Regulations.

For Dentists

Dentists and dental offices fall under the *transplantation* category for establishments as described in the previous section. **Dental offices that perform transplantations and don't further distribute CTOs to other dental practices do NOT need to register with Health Canada.**

It is important to note that **dentists who receive transplant products directly from a manufacturer in the United States for use in their individual or group practice are not considered "importers" and do NOT need to register with Health Canada.** However, if a dentist is distributing the transplant products to other dentists in the community, all the provisions of the CTO Regulations that apply to an establishment that imports and/or distributes would apply, including the need to register with Health Canada.

Also, in situations where a dentist has unused transplant products, he or she is not permitted to distribute the products to other dentists in the community without being registered with Health Canada.

Exceptional Distribution

The CTO Regulations (Section 40) cover the unlikely situation where a transplant dentist may authorize the distribution of a CTO from a source establishment that has not been

determined safe for transplantation. **This is known as *exceptional distribution* and is unlikely to occur in the case of dental procedures.** Please see CTO Regulations for additional information at: <http://laws.justice.gc.ca/eng/SOR-2007-118/page-1.html>.

Record Keeping

In general, recorded information is required to maintain the chain of distribution of the CTO, allowing it to be traced forward to any recipient or back to the donor, if necessary. For this reason, dentists may wish to maintain a separate log or record for transplant cases, in addition to the dental record/chart, so as to facilitate the identification of transplant recipients in the event of an inquiry.

Every dentist or dental office must ensure that the *donor identification code* is a component of its record system (Section 60 of CTO Regulations). The donor identification code is an identifier, assigned by a source establishment, that corresponds uniquely to all CTOs from that donor processed by, or on behalf of, the given source establishment.

Dentists must keep records with respect to CTOs which they transplant that contains the following information:

- a) a description of the transplanted CTOs (refer to the CTO package insert);
- b) the donor identification code (refer to the CTO interior label and package insert);
- c) the registration number of the source establishment (refer to the CTO package insert and exterior label);
- d) the notice of exceptional distribution, if any, and confirmation that the donor suitability assessment was completed as required by Section 42 (unlikely to occur in dental practice);
- e) information that allows the identification of the recipient; and
- f) documentation of any errors, accidents and adverse reactions and their investigation in connection with those CTOs and any corrective action taken.

These records must be retained for 10 years.

Informed Consent

Although informed consent is not part of the CTO Regulations, dentists are reminded of the requirement to fully inform patients of the procedures and transplant materials that will be used during surgery.

Summary

In summary, the CTO Regulations are designed to minimize the potential health risks to Canadian recipients of human CTOs. The provisions of the CTO Regulations that are most applicable to dentists are:

- **Source Establishment:** Only obtain transplantation material that is processed from an establishment registered by Health Canada and that is determined safe for

transplant,

- **Informed Consent:** Obtain informed consent from patients who receive CTO transplants,
- **Records:** Ensure that record-keeping procedures capture all the required information, which includes the donor identification code, in order to be able to trace the transplant material from its source to the recipient,
- **Reporting:** Report suspected errors, accidents and adverse reactions to the source establishment and its distributor and quarantine products, when applicable.

Questions?

If you have any questions concerning this guidance document, please contact Dr. Euan Swan, manager of dental programs, at eswan@cda-adc.ca