

Frequently Asked Questions Regarding Transplants in Dentistry

Transplant Types and Graft Materials

1. What are the types of transplants used in dentistry?

There are basically 4 different types of transplants or graft materials used in dentistry:

1. *Autografts* involve material obtained from the same individual receiving the graft.
2. *Allografts* involve transplants between genetically different individuals and are referred to as allogeneic transplants.
3. *Xenografts* involve transplants between different species.
4. *Alloplastic grafts* are man-made from synthetic materials.

Health Canada Regulations

2. Are there federal regulations concerning transplantation that affect dentistry?

Yes; Health Canada's *Safety of Human Cells, Tissues and Organs for Transplant Regulations* regulate the use of allografts used in dentistry (i.e., transplantation of minimally manipulated human cells and tissues).

3. Are there federal regulations concerning transplants involving xenografts (e.g., bovine bone) and alloplastic grafts (i.e., synthetic material)?

Xenografts and alloplastic grafts involve transplantation of non-human products and are regulated by Health Canada's *Medical Devices Regulations (1998)*.

Transplant Establishments

4. What is a transplant establishment?

A transplant establishment is a person, a partnership or an unincorporated entity (or part of any of these) that carries out the transplantation of human cells, tissues, or organs.

5. Is a dentist/dental office considered a transplant establishment?

Yes, if the dentist/dental office is providing allografts (allogeneic transplants) to patients.

6. Does my dental office or clinic need to be registered with Health Canada as a transplant establishment?

No, provided transplant products are not distributed to other dental practices.

7. In my dental practice we provide xenografts (e.g. bovine bone) and alloplastic grafts (i.e. synthetic material) to patients. Is my dental practice considered a transplant establishment?

No. Because xenografts and alloplastic graft products are processed from non-human material, they are considered to be medical devices and are regulated under *Medical Devices Regulations (1998)*.

Registered Suppliers of Allograft Material

8. How can I be sure that my supplier of transplant material is registered with Health Canada?

A registered supplier will have a Health Canada registration number on the package insert and exterior label of its transplant product(s).

9. Where should a dental office obtain material for transplantation?

Material for transplantation should only be obtained from a source establishment registered with Health Canada.

Importation of Allograft Material

10. If my dental practice imports transplant products directly from a source establishment in the United States, am I considered an importer by Health Canada?

Dentists who receive transplant products directly from a manufacturer in the US for use in their individual or group practice are not considered “importers” and do NOT need to register with Health Canada—unless a dentist is distributing the transplant products to other dentists in the community. In that case, all the provisions of the regulations that apply to an establishment that imports and/or distributes would apply—including the need to register with Health Canada.

Donor Identification Code

11. What is a donor identification code?

The donor identification code is a unique identifier assigned by the source establishment that corresponds to all the cells, tissues, and organs from a donor. This code is found on the product interior label and package insert.

12. Why is the donor identification code important?

The donor identification code is important as it allows the transplant material to be traced forward to any recipient or back to the donor, if necessary.

Dental records of patients receiving allografts (allogeneic transplants) must include the donor identification code.

13. Where can I find the donor identification code?

The donor identification code is found on the product interior label and on the package insert.

Informed Consent

14. What information needs to be provided to patients regarding allografts (allogeneic transplants)?

Although informed consent is not part of Health Canada's *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*, dentists have an obligation to fully inform their patients of the procedures and transplant materials that will be used during surgery as part of informed consent.

Additional Questions?

If you have more questions, please contact Dr. Euan Swan, manager of dental programs, at eswan@cda-adc.ca.

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