



Royal College of
Dental Surgeons of Ontario

Ensuring Continued Trust

BULLETIN

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TO: ALL RCDSO MEMBERS

URGENT INFORMATION

November 1, 2005

IMPACT OF RECALL OF HUMAN TISSUE USED FOR TRANSPLANTATION

On October 26, 2005, both Health Canada and the United States Food and Drug Administration (FDA) issued notices to advise the public about the voluntary recall of tissues products used in implants and grafts. These tissues were recovered by Biomedical Tissue Services of Ft. Lee, New Jersey.

As Health Canada stated in its notice, the tissue donors may not have met Canadian donor eligibility requirements and may not have been properly screened for certain infectious diseases. Health Canada currently estimates that approximately 300 tissue products originating from Biomedical were imported into Canada. Most of the implicated bone and skin products would have been implanted or grafted during dental procedures.

Both Health Canada and FDA have stated that the risk from the use of these products is considered to be low, as tissues are routinely processed using methods that help to reduce the risk of infectious disease. However, the actual infectious risk is unknown. To date, no known adverse events from these products have been reported in Canada or the United States.

While Health Canada, the FDA and the US Centers for Disease Control and Prevention (CDC) believe the risk to be low, precautionary measures are being recommended.

The College is sending you this urgent notice to make certain that you have received this information, and to provide you with guidance and assistance in protecting the health of your patients.

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The College suggests that you take the following steps:

1. Identify if any of the tissue products that you have ever used came from the distributors involved. If so, stop using these products and notify the distributor.

The following companies have all agreed to a voluntary recall of all products that were produced using tissues from Biomedical:

- Tutogen Medical Incorporated, which has sold products in Canada to Zimmer Dental of Mississauga, and Mentor Medical Systems of Canada Inc. of Oshawa;
- LifeCell Corporation, which has sold products in Canada to BioHorizons of Markham and Biogenics Inc. of Toronto;
- Regeneration Technologies Incorporated, which has sold products in Canada to Laswell of Milton and Medtronic of Canada Ltd. of Mississauga.

Dentists who have imported tissue products directly from a US supplier should consult the US Food and Drug Administration Web site for a list of US companies affected. The Web site is www.fda.gov.

2. Contact your distributor directly to determine if you have received products subject to the recall.
3. Notify all patients who may have ever received these tissue products and recommend infectious diseases testing. The College has provided a sample letter that you may want to use for this purpose.

Health Canada is advising that the following are the diseases to be tested for:

- HIV-1 and 2 (the viruses that cause AIDS);
- hepatitis B virus (HBV);
- hepatitis C virus (HCV);
- human T-cell lymphotropic virus (HTLV I and II);
- syphilis.

4. Make a written record of your communication with each patient in your patient records, including the date and method of contact.

5. Keep a comprehensive list of the patients you contact.

6. If you believe that you or your staff have come in contact with tissues involved in the recall, you and your staff may choose to have the same infectious testing done.

7. You may also wish to keep records of costs incurred by you in the event that reimbursement becomes available from those responsible at a later date.

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New Information

Health Canada is continuing to work with the FDA on a priority basis to obtain more information about the extent of the problem, the risk, and those impacted in order to monitor the recall in Canada.

Further public health notices will be issued as needed. This information, as it is released, would be posted on the Health Canada Web site at www.hc-sc.gc.ca.

College Contact

If you have any questions, please contact the following College staff:

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SAMPLE LETTER TO PATIENTS

RE: TISSUE RECALL

(Please reproduce this letter on your office letterhead.)

Dear Patient,

It has recently come to my attention that both Health Canada and the United States Food and Drug Administration have issued notices that there may be a problem with some tissue products imported into Canada from the United States. These products are used in implants or grafts during dental procedures.

Health Canada, the United States Food and Drug Administration and the US Centers for Disease Control and Prevention believe the risk to be low, as tissues are routinely processed using methods that help to reduce the risk of infectious disease.

However, out of an abundance of caution, I am contacting all of my patients who may have received the tissue products involved in this recall to provide them with advice.

Health Canada is advising that all patients who received these tissue products to have infectious disease testing for the following:

- HIV-1 and 2 (the viruses that cause AIDS);
- hepatitis B virus (HBV);
- hepatitis C virus (HCV);
- human T-cell lymphotropic virus (HTLV I and II);
- syphilis.

Of course, I would urge you to contact your personal physician if you have any concerns about your current health, and wish to make arrangements to have these tests performed by your physician or at your local public health unit.

Again, this information is being provided as a precaution only. If you have any questions, please feel free to call me at my office (*insert your phone number*), as your continued good health is my highest priority.

Yours truly,

(sign each letter)