

Toronto Academy of Dentistry Winter Clinic Panel Discussion on Grey Market and Counterfeit Dental Materials

Shady Materials: There's More than Meets the Eye

Patients trust dentists to provide the best care possible, and dentists need to be able to trust that the dental materials they use perform as they were intended to. Elaborate safeguards are in place at different stages of the journey of a dental material from its conception to delivery to a dental office. However, a number of events in recent years indicate that unscrupulous operators can subvert these safeguards and bring either illegal or counterfeit dental materials to market.

The American College of Dentists, Ontario Chapter, gathered an expert panel in Toronto, Ontario, last November to explain how the safety and effectiveness of materials is assured and to highlight things to watch out for when buying materials. Using resin composite as an example, the panellists discussed how to ensure the safety and legitimacy of dental materials throughout the supply chain, from the scientists who create the resin composite to the dentists who place it in patients' mouths.

Dr. Cal Torneck, immediate past-president of the American College of Dentists, Ontario Chapter, introduced the panellists: Dr. Paul Santerre, associate dean of research at the University of Toronto and a world-renowned researcher in the field of composite materials; Dr. Arthur Conn, dental advisor with the Medical Devices Bureau of the Health Products and Food Branch of Health Canada; and Mr. Bernie Teitelbaum, executive director of the Dental Industry Association of Canada. Dr. John O'Keefe, editor-in-chief of the *JCDA*, moderated the discussion.



Dr. Paul Santerre:
*What dentists should
remember and apply from
their DDS training in
biomaterials*

Composite materials are multi-component formulations that have evolved over decades of research, development and testing to improve quality and overcome such issues as low degrees of polymerization, the impact of degradation products on tissues, premature breakdown in clinical wear settings, and poor mechanical and handling properties. The high quality of a material and the documentation associated with it are reflected in its price.

Every time dentists consider a new product or supplier, they must apply the fundamental

biomaterial science training they received in dental school. They should always ask to see the Material Safety Data Sheet (MSDS) for any new material they consider using.

It is not difficult for an unscrupulous operator to source the raw materials that are used to create composite restorative materials, and counterfeit composite materials can easily find their way onto the market. The main problem with counterfeit materials is that their handling properties and behaviour post-insertion may be dramatically different from those of legitimate products, leading to embarrassing or potentially harmful failures. To avoid this situation, dentists should reassure themselves that the documentation trail for any product they purchase leads directly back to a legitimate manufacturer who follows the appropriate Canadian regulations for medical devices and dental materials.

The panellists' narrated PowerPoint presentations on these topics are available on CDA's website under *News and Events* at: www.cda-adc.ca/en/cda/news_events/media/dentistry_news/2008/02_21_08.asp.



Dr. Arthur Conn:
*Regulation of medical
devices and dental
materials in Canada*

Health Canada's authority in medical device regulation is through Canada's Food and Drugs Act and the Canadian Medical Devices Regulations. Almost everything a dentist would use in daily practice is regulated under some aspect of medical devices regulation.

In the early 1990s, Health Canada began employing a risk-based system of regulation of medical devices, devoting a higher degree of pre-market scrutiny to devices of greatest risk. There are 4 categories of risk, from 1 to 4, with 1 being the lowest. Only risk classes 2, 3, and 4 require a licence.

Central nervous system and cardiovascular devices, such as shunts and pacemakers, devices manufactured or derived from animal or human tissues and bone substitutes containing bovine collagen are all Class 4. Endosseous dental implants, joint replacement devices, synthetic bone substitutes and dental restorative materials, which include composite resin, are Class 3. Hand instruments, extraction forceps, dental units, battery-operated toothbrushes and orthodontic elastics are considered Class 2.

Health Canada regulates the manufacture, importation and sale of medical devices, but not the use of these products. A manufacturer must apply for a

medical device licence for a device to be authorized for sale in Canada.

In the application process, the manufacturer provides Health Canada with a pre-market review document that includes appropriate objective documentation proving that the new material is effective and safe in accordance with Canadian medical devices regulation.

This pre-market review document contains background information about the product, including a description of the device, its chemical composition, physical and mechanical properties, the design philosophy and marketing history of the product and any incident reports. It would also contain a summary of safety and effectiveness clinical and preclinical studies performed on the product, as well as any appropriate labelling information that includes warnings, precautions, any purposes and uses for which the device is manufactured, instructions for use, expiry date and MSDS. Manufacturers must also produce a certificate indicating that their quality systems conform to ISO 13485 before Health Canada will even review the application for licence.

A searchable database of both legitimate dental materials and companies that are authorized to import and sell those materials is available on the Medical Devices Licence Listing website at www.mdall.ca. When a company has an establishment licence to sell a product, this attests that there are procedures for distribution records and recalls, as well as mandatory problem reporting. If a company or dealer does not have an establishment licence, that's when dentists run into problems.

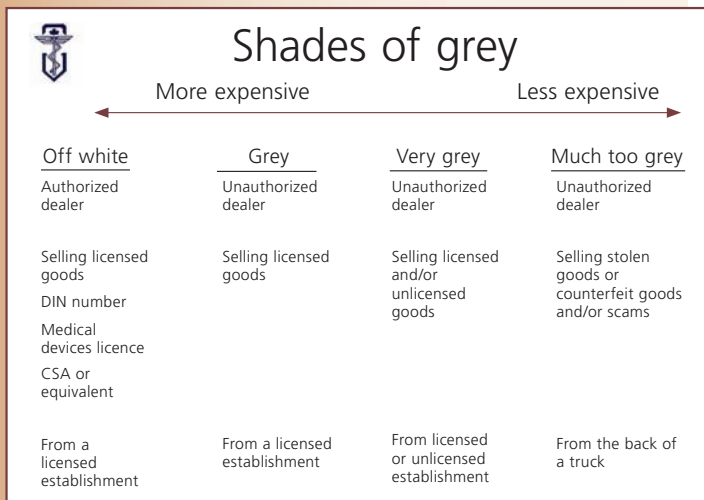


Mr. Bernie Teitelbaum:
Grey market in Canada

Dentists are presented with choices of dental materials from a variety of dealers selling products that range in price. If the materials considered are at the most expensive end of the spectrum, it is likely that dentists are buying from an authorized dealer with a Health Canada establishment licence.

This dealer will have products with DIN and lot numbers, medical devices licences, and in the case of equipment, a Canadian Standards Association approval. All of these criteria help ensure dentists have an avenue of recourse if problems arise with a product.

At the other end of the spectrum are dealers who sell goods "off the back of a truck," which may be stolen or counterfeit. In this type of situation it is always "buyer beware." To prevent experiencing potentially expensive or embarrassing problems as a result of using questionable materials, the best advice is to buy only from people you know. Check to make sure that all manufacturers and dealers



have a valid establishment licence. Dentists should make an inventory list of all the consumable products they use and check www.mdall.ca for product licences on a regular basis.

Besides checking for valid establishment and product licences, dentists who buy from a dealer they are not familiar with should look closely at packaging, logos and product name, and ensure that product logos or regulatory markings aren't defaced and that bar codes and expiry dates aren't missing. The equipment should be CSA approved; otherwise, dentists run the risk of not being insured in the event of malfunction or damage. Finally, dentists should not provide credit card information to a dealer they do not know. ➤

Resources

Information on establishment licences from Health Canada
www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/index_e.html

Medical Device Licence Listing
www.mdall.ca

Drug Products Information
www.hc-sc.gc.ca/dhp-mps/prodpharma/index_e.html

CDA Resource Centre

Resources available exclusively to CDA members

For the latest clinical, practice management and oral health research, managed by knowledgeable Resource Centre staff. Access a vast network of medical and dental libraries and information sources.

Literature Search and Article Photocopy Requests

The Resource Centre's skilled reference staff will search MEDLINE and other sources on your behalf or assist you with your own literature search for information and articles on any dental or medical topic. Get copies of full-text articles of interest for only \$9 per article.

Cochrane Library

Convenient direct access to the Cochrane Library, the best single source of the highest quality research studies and current evidence on clinical treatments. Access all 7 international databases, including the *Cochrane Database of Systematic Reviews*, considered the gold standard in evidence-based health care research.

eTOC

This easy-to-use email service lets you receive tables of contents from publications you need to stay current. Make your eTOC selections from the more than 250 publications received by the Resource Centre, then request articles of interest to you.

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For more information go to: www.cda-adc.ca/resource_centre.

