

Tip Sheet for Dentists Concerned about Lead Contamination

I am a general dentist and have just seen a television news story about a dental crown manufactured in China that was contaminated with lead. I am concerned about lead contamination. I am also concerned for the safety of my patients. What can I do?

First and foremost, call the dental laboratory that you use in your practice and ask the following questions:

- Do you outsource any part of my work to other labs?
- If yes, specifically what work of mine is outsourced?
- Do you outsource any part of my work to a foreign lab?
- If yes, will you provide me with the FDA registration number of foreign lab doing my work?
- Will you also provide me with your registration number with the FDA as an “initial importer,” “re-packager” or “re-labeler?”
- Have you actually visited the foreign lab to which you are outsourcing my work?
- Will you provide me with documentation that the materials used in the work you outsource are FDA approved and compliant with all ANSI and ISO standards?
- Will you fill my detailed lab prescription as written, regardless of where my work is fabricated?
- Do any of the materials you use to fabricate my work contain lead?
- Will you provide me with a document detailing the materials used in my work?
- Do you have products liability insurance or other insurance that will protect me against claims for injuries allegedly caused by dental restorations coming from your lab?

Your dental laboratory should be able to answer each of these questions to your complete satisfaction.

Reasoning behind the questions:

- *Some labs outsource domestically, as well as internationally.*
- *Most of the outsourcing to foreign labs is crown and bridge.*

- *Foreign outsourcing is still a relatively small share of the market, estimated to be approximately 15-20%.*
- *A foreign lab importing to the US must be registered with the FDA.*
- *Domestic labs that import, re-package or re-label must also register with the FDA.*
- *A site visit may imply a higher level of “due diligence” by the domestic partner.*
- *Labs should stand behind the material content of the outsourced work.*
- *Dentists should be as specific as possible, designating components and brands in their prescriptions. Labs should fill dental prescriptions exactly as written, and inform dentists in advance of any substituted materials.*
- *There is no justifiable reason to use lead in dental materials.*
- *Labs should be able to provide you with detailed written statement of assurance.*

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