

### Information for Patients About Dental Amalgam Fillings

#### What Is Dental Amalgam?

Dental amalgam, sometimes called a "silver-filling" due to its appearance, is a mixture of mercury, silver, copper, tin and zinc used to fill cavities in teeth. Dental amalgam is approximately half (50%) mercury, by weight.

#### Is Dental Amalgam Safe?

Dental amalgam fillings may release small amounts of mercury in the form of a vapor (gas), depending on the number and age of existing fillings, and actions such as tooth grinding and gum chewing. When a new amalgam filling is placed or an old filling is removed, patients and healthcare providers may experience a temporary increase in exposure to mercury vapor. While there are no known health risks associated with ingestion (swallowing) of small particles of dental amalgam, inhaling (breathing in) mercury vapors may be harmful in certain patients.

In general, people with multiple dental amalgam fillings may have slightly higher mercury levels in their blood or urine, however, they usually remain at a level considered safe. Studies on people with dental amalgam do not show conclusive evidence that dental amalgam causes harmful health effects in the general population.

## Who Should Be Concerned About Dental Amalgam?

Certain people, including women who are pregnant or who are planning to become pregnant, nursing mothers, children (especially those under the age of six), people with a known allergy to mercury, and people with neurological impairment or kidney dysfunction, may be more susceptible to the effects of exposure to mercury from dental amalgam and may be at greater risk for adverse health effects. Little information is known about the potential health effects of mercury vapor exposure from dental amalgam on these groups of people.



As such, if you are a person who is in one of the highrisk populations identified and need a new filling, the FDA recommends you avoid dental amalgam if possible and appropriate. Talk to your dental provider about your health history and other available treatment options for fillings.

- Women who are pregnant or planning to become pregnant. Placement of new amalgam fillings in a pregnant mother may result in high, transient spikes of mercury exposure to the mother and fetus. Some studies have shown a relationship between the number of amalgam fillings a mother has and mercury levels in umbilical cord blood. Results from these studies did not identify any certain associations with harmful health effects; however, the data is very limited.
- Nursing mothers. The amount of mercury in breast milk is typically very low. Some studies have reported a relationship between the number of amalgam fillings a mother has and the amount of mercury in breast milk. The very few, limited studies that have been conducted to evaluate possible harm to infants and children exposed to dental amalgam mercury as a result of breast-feeding did not identify any definite associations with harmful health effects.

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- Children, especially those under the age of six. Clinical studies in children ages six and older have not found a definite connection between the use of dental amalgam and harmful health effects. Studies on children under the age of six are very limited. The developing neurological systems of children may be especially sensitive to exposure to mercury vapor.
- People who are more sensitive to mercury or other components of dental amalgam. Some people may have an allergy or sensitivity to mercury or other components (e.g., silver, copper, tin or zinc) of dental amalgam and may report or experience health effects, including allergic reactions and oral ulcers, as well as more generalized symptoms, after placement of an amalgam filling.
- People with neurological impairment or kidney dysfunction. Studies show mercury is localized in certain tissues of the body including the brain and kidneys. Very limited clinical information is available about possible health effects of mercury vapor exposure on individuals who already have kidney and/or neurological impairments.

Although a direct correlation between mercury from amalgam and possible harmful health effects has not been established, and there may be cumulative effects from exposure to mercury from other sources such as the environment or diet, some signs or symptoms of excessive mercury in the body may include:

- Mood disorders (for example, anxiety, depression, irritability)
- Sleep troubles or disturbances
- Fatigue (feeling tired)
- Memory troubles or disturbances
- Tremors (shaking)
- Difficulties with coordination
- Visual changes
- Changes in hearing

### Should Dental Amalgam Fillings Be Removed?

If your filling is in good condition and your dentist or health care professional says there is no decay beneath the filling, removal of your amalgam filling is **not recommended**. This is because removing intact amalgam fillings may result in unnecessary loss of healthy tooth structure and potentially exposes you to a temporary increase in mercury vapor released during the removal process. Intact amalgam fillings in anyone, including those of greater risk such as pregnant or nursing mothers and children, should not be removed for the purpose of preventing any disease or health condition, unless considered medically necessary by a health care professional. If you have a health condition (especially sensitivity or allergy to mercury, or neurological or kidney disease), you should discuss the need for removal and replacement with your dentist or physician.

## What Other Materials Can Be Used for My Filling and What Are Their Benefits and Risks?

The use of dental amalgam has been declining through the years, with materials such as resin-based composites and glass ionomers (sometimes called "porcelain", "resin" or "white fillings") being more widely used. The durability of these alternative materials has improved since they were first developed, but may not reach that of dental amalgam fillings, especially in areas with higher biting forces or wear and stress from chewing, such as the back teeth (molars). Dental amalgam has advantages over resin-based materials in certain clinical situations, for example:

- When a patient is identified as being at higher risk for tooth decay;
- When there is a need for large fillings in posterior (back) teeth where biting forces are high; and
- Where moisture can present a problem for certain placement such as near the gumline.

Although resin-based materials may require more time for placement, they typically require the removal of less

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healthy tooth structure for placement, compared to dental amalgam. In addition, resin-based materials offer the added benefit in that they are color-matched to tooth structure and do not contain any heavy metals. However, resin-based materials also have risks associated with their use, with primary concerns being potential exposure and hypersensitivity to certain chemicals such as methacrylate and how long they will last (longevity).

If you need a filling, discuss all treatment options with your dental provider, including the benefits and risks of using dental amalgam and other dental restorative materials, to help you make an informed decision. If you are concerned about mercury exposure from dental amalgam, resin-based materials should be strongly considered. The decision about what material to use to fill cavities in teeth is one that should be made between you and your dental provider (and physician if needed).

The durability of any filling or tooth depends on many factors besides dental filling materials. To help your teeth and fillings last as long as possible, you should maintain a healthy diet, proper oral hygiene, and regular dental checkups.

# What If I Have Adverse Reactions with a Dental Amalgam Filling?

If you believe you have experienced **adverse reactions** from treatment with dental amalgam, you should discuss this with your dentist or physician and report it to the FDA's MedWatch program at 1-800-332-1088 or <a href="http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm">http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm</a>.

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