



Restricting the Use of Dental Amalgam in Specific Patient Groups

Discussion Points for Dental Professionals

This document provides further explanation of aspects of the restrictions on the use of dental amalgam for the dental team, to support discussions with patients and parents or carers.

The aim of this advice document is to support dental professionals in interpreting and implementing the restrictions on dental amalgam use. The information presented does not override the healthcare professional's right, and duty, to make decisions appropriate to each patient, with their valid consent. It is advised that significant departures from this implementation advice, and the reasons for this, are documented in the patient's clinical record.

What are the new restrictions on the use of dental amalgam and why are they being introduced?

New regulations in the European Union (EU) that restrict the use of mercury came into force in 2018. These regulations are part of a worldwide agreement to reduce global environmental pollution caused by mercury released during the production, use and disposal of mercury products, such as dental amalgam.

Mercury is a naturally occurring element that can be released into the environment both from natural sources and as a result of human activity. The released mercury persists in the environment and can accumulate to toxic levels and enter the food chain. Worldwide recognition of the serious impact of mercury pollution led the United Nations Environmental Programme (UNEP) to develop policies for a global reduction in mercury use. This became the Minamata Convention on Mercury. The Convention was adopted in 2013, has been agreed and signed by almost 130 countries, including Malta, and entered into force in August 2017. The aim of the Convention is to reduce the trade and supply of mercury by preventing its unnecessary use in products and manufacturing processes, with the overall objective of reducing environmental mercury pollution and the risk to human health.

There is no evidence that dental amalgam presents a direct health risk to individuals who have amalgam restorations. However, when released into the environment, the mercury that is stably bound within dental amalgam can be converted by microorganisms into methylmercury- a form that can accumulate to toxic levels in marine life and enter the human food chain. Therefore, by contaminating the environment, dental amalgam can contribute indirectly to the risk to human health from mercury. Reducing the production, use and disposal of dental amalgam will help to reduce this indirect risk.

According to the new regulations, the use of dental amalgam is no longer allowed for the treatment of children under 15 years of age, of pregnant or breastfeeding women or of primary teeth in any patient, unless the dental practitioner thinks that it is strictly necessary. These restrictions on the use of dental amalgam aim to help reduce environmental mercury pollution and are not a result of any safety concerns about amalgam restorations for dental patients. This regulation is a legal requirement as of 1 July 2018.

Why do the restrictions apply to these patient groups?

Children, pregnant and breast-feeding women have been specified by the EU for the current restrictions in dental amalgam use. Restricting the use of dental amalgam in any patient group will help to reduce mercury pollution, restricting the use in children in particular will contribute towards future amalgam free patients. The legally defined age limit for this is 15 years of age.

The avoidance, where possible, of dental amalgam use in pregnant or breastfeeding women is due to developing fetuses, infants and young children being generally considered to be at higher risk of theoretical harm, and so, while there is no evidence that dental amalgam restorations cause any harm to the health of patients, the precautionary principle of avoidance where possible applies to them.

Explaining why an amalgam restoration has been advised for a patient who is included in the restrictions.

It is recognised that in some situations, for some of the patients specified in the regulation, and despite the environmental concerns, the use of dental amalgam will be the only feasible treatment option to best meet the specific clinical circumstances and patient's needs. Examples include where there is an allergy or local adverse reaction to alternative materials or when it is not possible to obtain adequate moisture control or patient cooperation for the treatment required. In such cases, the patient and parent/carer should be informed of the reasons for the advice to have dental amalgam restorations and reassured that there is no evidence that the placement of a dental amalgam restoration is harmful to the health of patients, including those specified in the restrictions.

Dental amalgam restorations currently remain a treatment option for patients that are not specified in the new regulations and are considered to be safe.

Advice about the removal and replacement of dental amalgam restorations.

There is no evidence to suggest that existing dental amalgam restorations are harmful to patient health, including for children, unborn or breastfeeding babies. Therefore, there is no reason to replace clinically sound dental amalgam restorations, except in patients with an allergy or adverse local reaction to any of the components of dental amalgam. Removal of sound amalgam restorations can result in unnecessary loss of tooth material.

As a precaution, it is advised that the removal of dental amalgam restorations is best avoided during pregnancy. However, it would be reasonable to remove an amalgam restoration for urgent treatment, such as the relief of pain or infection.

This leaflet has been developed by the Health Amalgam Advisory Committee. This and other patient information is available on the Department of Health Regulation website.