

On the use of Amalgam for dental fillings in Sweden

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Content of this presentation

- **Short regulatory introduction**
- **Current use of Amalgams in Sweden**
- **A look into the future**

Regulatory framework



European framework

- Medical devices are regulated under the New Approach (umbrella) directive
- Europe has a post market surveillance system for Medical devices
 - Not a premarket approval system (compare FDA in USA, Drug regulation in Europe etc.)
- The manufacturer has full responsibility for the function and safety of their products
- Involvement from a third party for higher risk-classes (Notified Body). Dental Amalgams are subject to Notified Body involvement
- A device put on the market in one member state automatically has access to all other member states



**The CE-mark is applied by
the manufacturer!**

**It is not a sign of
"approval"**

1234



Notified Body ID number

**Mandatory on all new Medical Devices
within the EU and shall be affixed at
the entire product, that is:**

- the device**
- the packaging**
- the instructions for use**

The CE-mark signifies that

- **The Device is suitable (and safe) for its intended use**
- **The Essential requirements in the applicable Directives are met. Part of this is the fulfillment of the requirements of all applicable harmonized European standards**
- **The manufacturer has used one of several specified methods to show that the Essential requirements are met**





EU-directives for Medical Devices

- **AIMD 90/385/EEC** Active implantable MD
- **MDD 93/42/EEC** General devices
- **IVD 98/79/EC** In vitro diagnostics

Current situation

Sources of information

- **Swedish Ministry of Health and Social Affairs**
- **Swedish Ministry of Sustainable Development**
- **Swedish Chemicals Inspectorate**
- **Swedish National Board of Health and Welfare**

Data quality

There is (since 2001) no central (governmental) register for the use of different dental filling materials.

The data presented in a December 2005 study by the Swedish Chemicals Inspectorate is based on information from the major companies distributing dental filling materials in Sweden. The study is said to cover 80% of all the dental filling materials used in Sweden.

Overview

- **Dental amalgams have, in Sweden, been replaced almost totally by other materials over the past 7 years**
- **980 kilograms of mercury was sold for use in amalgams in 1997. This figure was reduced to approximately 100 kilograms in 2003**
- **There is no indication that this figure has, since then, increased**

Shares (by weight) of dental filling materials in Sweden 2005 (for direct techniques)

Composites	78%
Glass ionomers	13%
Amalgams	6%
Compomers	3%
Ceramics	<1%

Note that since composites are lighter than amalgams one kilogram of composites will fix many more teeth than one kilogram of amalgam

Rationale for reduced use

- **As reported, the use of dental amalgams in Sweden is very low**
- **Mechanisms explaining the reduced use of amalgam**
 - **Increased awareness of the negative environmental impact of mercury**
 - **The Swedish national health insurance program is, since 1999, not covering direct procedures including amalgams**
 - **Possible impact on health has not been ruled out (the “precautionary principle” is applied, not scientific data)**
 - **Health concerns regarding dentists**

Science based attitude?

- **According to the Swedish view there is, today, no conclusive scientific clinical data demonstrating a connection between the use of dental amalgams and medical problems**
 - the above does not apply to contact allergies
- **The possibility that reported medical problems are, for some patients, related to dental amalgams is not excluded**

What's next?

What is in the pipeline?

- **A complete prohibition for the use of mercury in Sweden is introduced January 1, 2007**
 - this will include amalgams containing mercury
 - the decision is based on environmental concerns
- **Dental amalgams will still be allowed after this date for some procedures performed in hospital based dental clinics (for exceptional cases only)**

What is in the pipeline? (contd.)

- **The Swedish Government has commissioned the National Board of Health and Welfare (NBHW) to allocate money (€1 million until 2009) for research and development of methods to handle the health problems that are associated with Dental materials**
- **The Swedish Government has also commissioned the NBHW to establish a national register for health- and side effects related to Dental materials (€1 million until 2010)**

Thanks!

The following slides will be used “on demand” only.

Used nomenclature of dental filling materials

Composites

Polymer resin based materials.

Used nomenclature of dental filling materials

Glass ionomers

Cement consisting of poly acrylic acid and acid soluble glass powder.

Used nomenclature of dental filling materials

Amalgam

An alloy of mercury and other metals.

Used nomenclature of dental filling materials

Compomers

Composite materials that are polyacid modified composites.

Used nomenclature of dental filling materials

Ceramics

Filling material mainly containing ceramic products.