

# ADVERSE REACTION REPORTING FORM

REPORTING OF SUSPECTED ADVERSE REACTIONS ASSOCIATED WITH DENTAL MATERIALS

Dental Biomaterials  
Adverse Reaction Unit

The adverse reaction reporting form must be completed by a dentist, dental hygienist or physician. The questionnaire covers the spectrum from specific reactions to non-specific, subjective reactions associated with dental materials. Although there is doubt about the degree and nature of reactions, it is nevertheless important that the form is completed and submitted. One form must be completed per patient who has reaction(s). Data (including the reporter's name) are stored in a database at the Dental Biomaterials Adverse Reaction Unit - NIOM for statistical analyses. We also want to get a report on possible reactions to materials that dental health personnel are exposed to in an occupational context (see occupational reactions next page).

**NB! The adverse reaction form alone does not apply as a referral.**

Name and address of the reporter:

Postal code.:

City:

Phone number.:

Email:

Completion date:

Clinic type:

Dentist, public

Dentist, private

Specialist in:

Dental hygienist, public

Dental hygienist, private

Physician, hospital

Physician, GP

Specialist in:

## Patient data

Gender:  Female  Male

Age:            years

General diseases/diagnoses:

Medications:

Hypersensitivity/allergy known:

Did the patient bring the reaction(s) to your attention?

Yes  No

The reaction appeared for the first time in which year:

How long after treatment did the reaction(s) occur?

Immediately     Within 24 hours     Within 1 week     Within 1 month     Months to years     Unknown

## Symptoms and findings

### Patient's symptoms

None

#### Intraoral:

- Burning sensation
- Pain/tenderness
- Taste disturbances
- Stiff/numb
- Dryness
- Increased saliva/mucus volume

#### Lips/face/jaws:

- Burning sensation
- Pain/tenderness
- Stiff/numb
- Skin reactions
- Temporomandibular joint problems

#### General reactions related to:

- Muscles/joints
- Gastrointestinal
- Heart/circulation
- Skin
- Eyes/vision
- Ear/hearing, nose, throat

Other:

#### Other symptoms:

- Fatigue
- Dizziness
- Headache
- Memory disorders
- Concentration disorders
- Anxiety
- Unease
- Depression

Other:

### Reporter's findings

None

#### Intraoral:

- Swelling/oedema
- White lesions
- Ulcers/blisters
- Rubor
- Atrophy
- Impressions in tongue/cheeks
- Amalgam tattoos
- Linea alba

Other:

#### Lips/face/jaws

- Swelling/oedema
- Ulcers/blisters
- Erythema/rubor
- Rash/eczema
- Palpable lymph nodes
- Temporomandibular joint dysfunction
- Decreased sensibility

Other:

#### Other findings:

- Swelling/oedema
- Urticaria
- Ulcers/blisters
- Rash/eczema
- Erythema/rubor

Set location:

**In connection with what type of treatment did the reaction(s) occur?**

- Fillings (direct technique)
- Inlays, facets
- Fixed partial dentures (crowns, bridges)
- Removable dentures (full, partial)
- Treatment of temporomandibular dysfunction
- Temporary treatment
- Root canal treatment
- Periodontal treatment
- Oral surgery
- Orthodontic treatment
- Preventive treatment

Other:

**What materials are suspected to be cause of the reaction(s)?**

- Amalgam
- Composite
- Compomer
- Glass ionomer
  - chemical
  - light cured
- Bonding materials ("primer/bonding")
- Cavity liners
- Fissure sealing materials
- Protective films (e.g. varnishes)
- Pulp capping materials
- Endodontic materials
- Luting materials
  - water-based
  - resin-based
- Metal ceramic (MK, PG)
  - metal/alloy
  - ceramic
- Materials for crowns/bridges/inlays
  - metal/alloy
  - resin-based
  - ceramic
- Materials for removable protheses
  - metal/alloy
  - resin-based
- Materials for intraoral orthodontic devices
  - metal/alloy
  - resin-based
- Materials for extraoral orthodontic devices
  - metal/alloy
  - resin-based
- Materials for treatment of temporomandibular dysfunction
- Materials for dental implants
- Impression materials
  - hydrocolloids
  - elastomers
- Temporary materials – fixed dentures
- Temporary materials – removable dentures
- Other temporary materials
- Consumables (e.g. gloves, cofferdam)
- Other materials

**Brand name and manufacturer**  
of the material(s) suspected to be involved in the reaction(s):  
Please attach Safety data sheets if available.

**The Adverse Reaction Unit use only**

Received: \_\_\_\_\_

Answered: \_\_\_\_\_

Registered: \_\_\_\_\_

Classified: \_\_\_\_\_

Sign: \_\_\_\_\_

**Occupational reactions**

The reaction(s) applies to dental health personnel in an occupational context (this is a matter that sorts under the Labour Inspection Authority (Arbeidstilsynet), but we want this feedback because it may also be relevant for reactions in patients).

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web: <http://www.niom.no>

Thank you for reporting.

**NIOM**  
Adverse Reaction Unit

**How does the reporter assess the relationship between the material and the reaction(s)?**

Dentist/ dental hygienist/ physician:

- Probable/Certain
- Possible
- Uncertain/no opinion

Patient:

- Probable/Certain
- Possible
- Uncertain/no opinion

**Referrals**

Is the patient referred for investigation/examination/treatment of the reaction(s)?

No

Yes, to

- Dental Biomaterials Adverse Reaction Unit)
- Dentist
- Dental specialist
- General practitioner
- Medical specialist or hospital
- Alternative therapist

Other: