

This form can be used for reporting of adverse effects of dental materials.

The form should be completed according to the professional judgement of the dentist, physician, or dental hygienist concerned.

The form covers a range of reactions, from obvious adverse reactions to non-specific, subjective reactions associated with dental materials.

A form should be submitted even when the association between the reaction(s) and the material(s) is uncertain or questionable. Use one form for each pertinent patient/person.

We would like to be informed on reactions to dental materials in dental personnel (se other side).

Name and address of the reporter:

.....

.....

Postal number:

City/Place:.....

Phone:.....

Today's date:

- Dentist: Dental hygienist
 Public Private

Specialist in:

- Physician
 Hospital Primary/private

Specialist in:

Patient information

The reporter's identification of the patient (no name or personal ID)

.....

Gender: Female Male

Age years

General diseases:

Present use of medicines, please specify:

Known allergies, please specify:

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

- Yes No

The reaction(s) occurred for the first time in what year?

How long after treatment did the reactions occur?

- Immediately within 24 hours within 1 week within 1 month months to years unknown

Patient's reactions and findings

Localization and description

Patient's description

(subjective symptoms):

- None

Intra-oral symptoms

- Burning sensation, smarting
 Pain, tenderness
 Taste disturbances
 Feeling of stiffness, numbness
 Dry mouth
 Increased salivation

Other:

Symptoms from lips, jaws, face:

- Burning sensation, smarting
 Pain, tenderness
 Feeling of stiffness, numbness
 Skin problems
 Symptoms from TM joint

Other:

General symptoms (related to):

- Muscles, joints
 Gastro-intestinal system
 Cardio-vascular system
 Skin
 Eyes, vision
 Ear, nose, throat

Other symptoms:

- Fatigue
 Dizziness
 Headache
 Memory disturbances
 Difficult to concentrate
 Anxiety, restless, depressed

Other:

Findings

(by reporter):

- None

Intraoral:

- Edema
 White mucosal changes
 Ulcers/vesicles
 Erythema
 Atrophy
 Impressions tongue/cheek
 Amalgam tattoo
 Linea alba

Other:

Lips/face:

- Edema
 Ulcers/vesicles
 Erythema
 Dermatitis/eczema
 Palpable lymph nodes
 Signs of TM joint dysfunction
 Decreased sensibility

Other:

Other findings: Localization:

- Edema:
 Urticaria:
 Ulcers/vesicles:
 Eczema/dermatitis:
 Erythema:

Other:

Type of treatment involved in the suspected reaction(s)

- Fillings (direct insertion)
- Inlays, veneers
- Fixed partial dentures (crowns, bridges)
- Removable dentures (full, partial)
- Treatment of temporo-mandibular disorders
- Temporary procedures, restorations
- Endodontic treatment
- Periodontal treatment
- Oral surgery
- Orthodontics
- Preventive procedures
- Other:

Type of material suspected to be involved in the reaction(s)

- Amalgam
- Composites
- Compomers (polyacid-modified composites)
- Glass ionomers (chemical light activated)
- Bonding materials ("primer/bonding")
- Cavity liners/bases
- Pit and fissure sealants
- Protective films (e.g. varnishes)
- Pulp capping materials
- Endodontic materials
- Luting materials (water based resin based)
- Metal-ceramic (metal/alloy ceramic)
- Materials for crowns, bridges, inlays (not metal-ceramic) (metal/alloy resin-based ceramic)
- Materials for removable prostheses (metal/alloy resin-based)
- Materials for orthodontics, intra-oral (metals/alloys resin-based)
- Materials for orthodontics, extra-oral (metals/alloys resin-based)
- Materials for treatment of temporo-mandibular disorders
- Materials for dental implants
- Impression materials (hydrocolloids elastomers)
- Temporary materials – fixed prostheses
- Temporary materials – removable prostheses
- Temporary materials – other
- Consumer goods (e.g. gloves, rubber dam)
- Other materials

Brand name and manufacturer

of the material(s) suspected to be involved in the reaction(s):

Causality assessment

How does the reporter assess the relationship between the material/treatment and the reaction?

- Probable/Certain
- Possible
- Uncertain

Patient's (or concerned person's) assessment of the relationship between the material/treatment and the reaction (if relevant):

- Probable/Certain
- Possible
- Uncertain

Referrals

Has the patient been referred for examination regarding the reaction(s) in question?

- No
- Yes, to a general practitioner
- Yes, to a dentist
- Yes, to a medical specialist or hospital
- Yes, to a dental specialist

Other:

Has the patient been examined regarding the reaction(s) in question?

- No
- Yes, by a general practitioner
- Yes, by a dentist
- Yes, by a medical specialist or at a hospital
- Yes, by a dental specialist
- Yes, by persons in complementary medicine

Other:

The reaction concerns dental personnel in professional activity.
(Explanation regarding Norwegian regulations concerning reporting of incidents related to occupational safety and health)

Additional forms required
Number:.....

Dental Biomaterials Adverse Reaction Unit,
Årstadveien 17, NO-5009 Bergen, Norway

Telephone: + 47 55586271
Facsimile: +47 55589862
E-mail: Bivirkningsgruppen@uib.no
<http://www.uib.no/bivirkningsgruppen>

Please note! This form is not a referral.

Thank you for your time, and we will appreciate your comments.

(Responsible for this draft:
Nils R. Gjerdet -- Gjerdet@odont.uib.no
On adverse reporting concerning dental materials:
<http://www.uib.no/ood/advrep/MAIN-Advrep.html>)