



FDI POLICY STATEMENT

Bioactive Restorative Materials

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Geneva, Switzerland

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CONTEXT

The term "bioactive" has become popular and is increasingly used in advertisements and in scientific publications to describe restorative dental materials. In addition, some journals include the term bioactive in their title. Many definitions for this term have been provided in the medical and dental literature,¹⁻⁴ but controversy remains concerning its use. Furthermore, so far, there is no description of this term issued by an international dental organization. Consequently, it is now necessary to have a description to prevent misuse of the term bioactive and thus protect dentists and patients, clarify the term for regulatory purposes and allow for future developments.

SCOPE

The term "bioactive" will be limited in this Policy Statement to restorative dental materials, including those used for direct or indirect restorations, non-adhesive and adhesive (bonding to tooth structures by micromechanical or chemical means) procedures, and for indirect and direct pulp capping.

DEFINITIONS

Restorative material: Material designed to be used for rebuilding or correcting the form and function of the tooth.

Indirect pulp capping: Dressing for conserving the vitality of the pulp of a tooth infected with a penetrating carious lesion, the complete removal of which could result in exposure of the pulp.⁵

Direct pulp capping: Dressing of an exposed pulp with the aim of maintaining pulpal vitality.⁵

28 **PRINCIPLES**

29 The prefix “bio” (Greek term for “living”), in this context, can be related to:

- 30 • the process/mechanism of action;
31 • the target tissues, here mainly enamel, dentine, pulp and bacteria/biofilms.

32 Whereas the term bioactive is neutral and can be applied to desired or undesired
33 effects, in daily dental practice, this term is generally attributed to desired, local and
34 intended effects. For this Policy Statement, such effects are repair (and
35 regeneration) of or other interaction with adjacent tissues, or an interaction with
36 bacteria/biofilm on or next to restorative materials.^{4,6,7}

37 According to the biological process/mechanism of action, three levels may be
38 distinguished:

- 39 • by solely biological means (e.g. through exogenous growth factors
40 or pharmaceuticals, which may be incorporated into dental restorative materials).
41 • by mixed biological and chemical means (e.g. through materials
42 inducing endogenous growth factor release/activation, such as calcium
43 hydroxide preparations, or through materials decreasing or preventing
44 bacteria/biofilms);
45 • by materials causing purely chemical effects (e.g. through ion release
46 from bioactive glass fillers).

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48 **POLICY**

49 The use of the term “bioactive restorative material” should be limited for material
50 advertisement/information to those materials that meet all five of the following
51 criteria:

- 52 • the mechanism is clearly defined and described (biological, mixed, chemical);
53 • a scientifically documented bioactive effect in vitro or in situ and most preferably
54 also in clinical studies;
55 • a stated duration of the effect, especially for antibacterial effects;
56 • no significant adverse biological side effects (including the development and
57 spread of antimicrobial resistance);
58 • the prime purpose, for instance, to be used to rebuild the form and function of
59 lost tooth substance or lost teeth, is not impaired, as demonstrated by data from
60 in vitro and clinical studies.

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62 **KEYWORDS**

63 Restorative materials, pulp capping, antimicrobials, ion release, growth factors

64 **DISCLAIMER**

65 The information in this Policy Statement was based on the best scientific evidence

66 available at the time. It may be interpreted to reflect prevailing cultural sensitivities
67 and socio-economic constraints.

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