

## General risks of dental treatments

- These risks are not specifically related to VITA products and their use, and are generally well known for all dental practitioners.
- Dental treatment and the integration of dental restorations entail the general risk of iatrogenic damage to hard tooth substance, pulp and/or oral soft tissue. The use of bonding systems and the integration of dental restorations involve the general risk of postoperative hypersensitivity.
- If the instructions for use for the products are not observed, the product characteristics cannot be guaranteed. A product defect and an irreversible injury to the natural hard substance of the tooth, the dental pulp and/or the oral soft tissue may result.
- The success of a tooth restoration always depends on how well it fits on the underlying tooth structure.
- The ability to produce a routinely smooth, sound and well-fitting restoration requires strict adherence to certain fundamentals.
- A deficient margin leads to plaque formation, resulting in gingival inflammation and marginal cracks, which can lead to secondary caries, sensitivity, gingival recession, cement dissolution and debonding or discoloration of the restoration.
- If restorations are overcontoured in the occlusal area, this can lead to increased forces and breakage. Overcontouring in the marginal area leads to recesses of dirt, which in turn can lead to increased plaque accumulation and plaque-induced gingivitis, and over time, periodontitis. The risk of secondary caries is increased by the active biofilm. Overcontouring in the lingual area can limit the function of the tongue.
- Inadequate polish or glaze can lead to microcracks in the restoration, which over the long-term clinical course results in the spread of cracks, fractures and chipping. Only instruments or materials that are suitable for the restoration material should be used for polishing and glazing.
- The preparation creates the risk of injury and/or overheating of the pulpal soft tissue. This can lead to irreversible pulpitis and death of the pulp, which must be treated with a root canal treatment or a root tip resection, and in the event of therapeutic failure, leads to tooth loss.
- If the biological width is disrupted during the preparation (i.e., the distance between the crestal alveolar bone and the restoration margin is too small, leading to chronic irritation of the gums and periodontal tissue), this can lead to recession and periodontal bone loss.
- During the try-in and insertion of the restoration, make sure the restoration is firmly secured in order to avoid inhalation into the lungs and any further risk. The restoration must be appropriately secured. A rubber dam, for example, provides a safe barrier between the work area and the respiratory tract.
- Our products must be used in accordance with the actual version of the instructions for use.
- Any misuse may cause damage, resulting from incorrect handling or usage.

- The user is furthermore obliged to check the product before use with regard to its suitability for the intended area of applications.
- We cannot accept any liability if the product is used in conjunction with materials and equipment from other manufacturers that are not compatible or not authorized for use with our product.
- If serious incidents have occurred in connection with the product, they must be reported to VITA Zahnfabrik H. Rauter GmbH & Co. KG, and the competent authority of the Member State in which the user and/or patient is established.