## **SCIENTIFIC INFORMATION**

## Grandio – Nanotechnology does not represent a risk

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Nanotechnology is considered one of the key technologies of the 21<sup>st</sup> century. Just like every other new technology, this one should also be critically analysed to determine possible risks associated with its use. A general statement is definitely not possible here, since nanotechnology is found in many, entirely different subareas, such as electronic semiconductors, optoelectronics, biochemistry and electroplating technologies. As a manufacturer of dental materials, we can, however, give the "all-clear" for this area.

What is actually "nano"? To begin with, this word is only a prefix that can be freely used and even be factually deceptive in advertising without being regarded legally as "misleading". A definition for its general linguistic use is thus impossible. Science, however, does provide an exact definition for itself: Particles with a diameter of 1-100 nm or 0.001 - 0.1 µm are called nanoparticles. The limit is also simple here, since this type of particle exhibits properties that clearly differ from the classical physics of larger particles.

Nano-particles can consist of entirely different materials, such as precious metals, oxides or plastics. The possible uses vary considerably and, to some extent, have nothing in common. Inorganic oxides are of primary interest for dental materials. Inorganic oxides have always been used as fillers, but they have special properties when nano-scaled: They do not increase the viscosity of liquid mixtures or raise the opacity. They facilitate higher filler contents with polishable particle sizes and are optically identical to the tooth.

Nano-technology is still a young science, since the particles and structures of this dimension can only be manufactured with great difficulty. Nano-scaled molecules themselves have been the basic elements of nature since the beginning of life and ubiquitous in every cell as DNA, protein or cell organelles. The size alone of nano-particles does not intrinsically represent a danger. There are nevertheless risks that can be justifiably discussed.

A possible danger from nano-particles always consists of two factors. First of all, the chemical composition should be considered, especially if there are toxic materials present. The second factor to consider is how and whether these particles can be released from the preparation; thus how their mobility is rated. If only one of the hazardous requisites of toxicity and mobility is not met, then a potential impairment of health from dental filling materials is sufficiently improbable.

Evaluation of the mobility:

The nano-scaled fillers in Grandio are imbedded in the plastic-resin matrix and not present as airborne dusts or aerosols, as are found in sprays. Ultimately, the nano-particles are covalently bonded to the resin when polymerised with light, i.e. they are polymerised to substantially larger molecules. There are thus no more existing, isolated nano-particles in the placed filling after polymerisation.



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Even the grinding dust from Grandio during finishing does not differ from the grinding dust from micro-composites. Nanoparticles, however, are always found in the grinding dust from hard materials; thus, even with the polishing and finishing of metal, ceramic or a real tooth. As a rule of thumb, it can be considered that the harder the material is, the finer the grinding dust will be. Grinding should be conducted under water, especially when it comes to grinding tooth enamel and ceramic; not only for heat transmission reasons, but also to bind the dust.

Evaluation of the toxicity:

The nano-particles in Grandio are comprised of pharmaceutical, pure silicon dioxide (quartz), the main component of nearly all glasses and natural minerals. Silicon dioxide is nontoxic and used as the negative standard in toxicological analyses. Biologically, nano-scaled silicon dioxide appears in some living organisms as a cytoskeleton (diatoms, radiolarians). Apart from its use as a remedy in the form of healing crystals, healing earth or dietary supplements, its effectiveness is scientifically questionable. It is found (E 551) in numerous foods, in addition to objects of daily use, such as drinking glasses and bottles.

Nano-particles in Grandio are neither toxic nor mobile. There is thus not even one theoretical risk from its presence in the composite. Since the material was the first type of dental filling material in this range, numerous tests were conducted as a precaution by a certified, independent laboratory. As anticipated, Grandio was unremarkable and classified as toxicologically safe. Several million fillings have been placed with Grandio to date and even in the dental surgery there has not been a single case where the material's toxicological safety came into question.

Conclusion: The nano-technology in Grandio brings many advantages to minimally invasive therapy for the conservation of teeth, without additional risk.

