

Product Information

Elemental Granulate

Oral Surgical Granulate



Thermoplastic, antibacterial, non-resorbable dental material.

Component	Concentration
Biocompatible Medical Grade Polymer	> 90.0%
Elemental Antimicrobial Additive	0% - 10%

Chemical description & components

This product is a mixture, composed of a polymer and of substances below the applicable classification limits for food, skin contact and FDA. None of the substances contained in the mixture are above the values fixed in Annex II of Regulation (EC) no1907/2006.

Recommended indications

Use Elemental Granulate for antibacterial mechanical coverage of oral surgical sites and chair-side creation of custom appliances.

Safety

Safety compliance of the antimicrobial additive confirmed for the use in medical devices and implants by third party regulatory experts. The technology also fully complies with EU and USA food contact regulations.

Antimicrobial Effectiveness

Polymers tested according to international norms ISO 22196, JIS Z2801 and ISO20743. The antibacterial performance ranges from >99% to >99.99999%.

Biocompatible & Non-Toxic

Antibacterial technology based on natural electrostatic repulsive properties of the trace element zinc (Zn^{2+}), present in the human body and essential to the human immune system. The technology does not contain toxic substances. There are no biocides, no chlorhexidine, no silver, no triclosan, no antibiotics, no nano-materials, toxic monomers or any other harmful chemicals.

Antibacterial, Bacteriostatic

There is no bactericidal substance migrating or leaching to act against bacteria. The functionality is purely due to the improved mechanical/physical property of the material surface. (fig. 1)

Hydroplastic, non-autoclavable

Elemental Granulate is hydroplastic. In hot water or sterile saline the material will become soft & mouldable and enables easy manual handling. Autoclaving the material will damage its handling properties. The recommended temperature of water/saline for preparing the material is +80°C.

Cooler water will result in less moldability and homogeneity of the material and a shorter working time. Do not heat up the Elemental Granulate to temperatures over 150 degree celsius as this may damage the product's inherent properties.

Working & setting time

Working & setting times depend on the amount of material used. The material begins to harden after 30 to 60 seconds. The material sets into a rigid material after approx. 2 minutes.

Remoldability

When put back in +80°C water or sterile saline, the material becomes soft again and remoldable.

Non-mucoadhesive

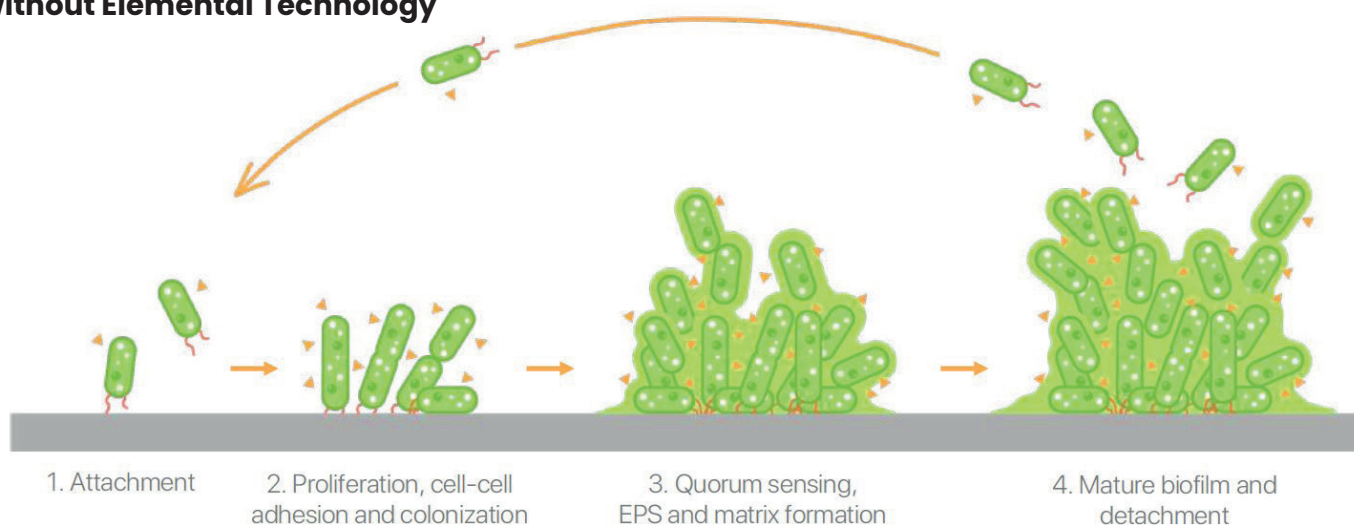
The material is not mucoadhesive. Always ensure stable retention in the mouth. Techniques for retention are available in the protocols.

Storage

Store Elemental Granulate in a dry area between 5-30 °C or 40-85 °F.

Fig 1.

Bacterial & biofilm growth without Elemental Technology



Bacterial & biofilm growth with Elemental Technology

