



**TECHNICAL DATA SHEET
HIGH ALLOY
DPFTPT-079**

1. GENERALITIES OF THE PRODUCT

High Alloy is an alloy for dental amalgam designed and produced by New Stetic for a successful clinical treatment for filling class I and II cavities on posterior teeth (molars and premolars).

High Alloy is a dispersed phase alloy with high silver content, which physical and chemical characteristics, together with a correct clinical procedure performed by the professional, guarantee an excellent restoration. The following are the most important aspects of product:

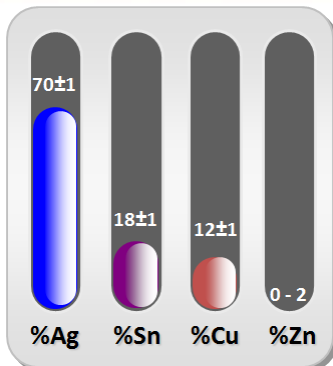
- ✓ Its chemical composition enables compliance with regulatory technical parameters.
- ✓ The mixture of spherical and lathe-cut particles produces a plastic amalgam, firm however when making the condensation process, allowing applying enough pressure to ensure proper sealing of the tooth cavity.
- ✓ Enough time for the professional to perform the work a good restoration.
- ✓ High mechanical properties according to the requirements imposed by a restoration on posterior teeth.
- ✓ Excellent manipulation characteristics at each restoration process stage.
- ✓ Pre-dosed capsules that provide security during the grinding stage, and in various doses according to the size of the cavity to be sealed.

2. INFORMATION ABOUT COMPOSITION

In an amalgam alloy, the chemical composition is a key factor as it will determine the restoration's physical and mechanical properties. *High Alloy* product is manufactured thinking about this need, so its composition ensures compliance with regulatory requirements and also great manipulation properties.

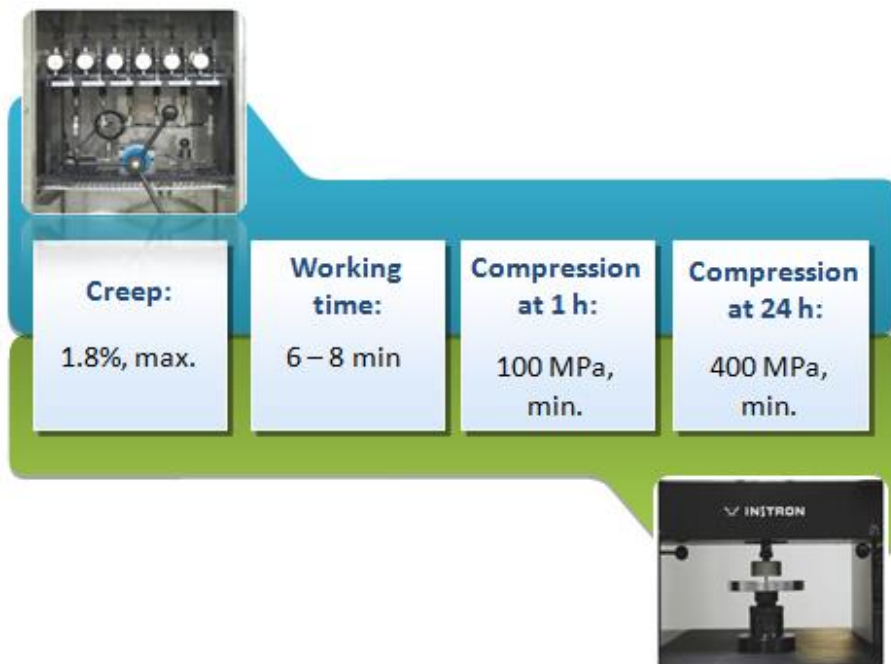
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3. PROPERTIES OF THE PRODUCT

The product properties are guaranteed by virtue of its manufacturing is performed according to a standardized and certified process according to international standards ISO 9001 and ISO 13485. In addition, the finished product is verified to comply with regulatory technical requirements by using calibrated and specialized equipment.

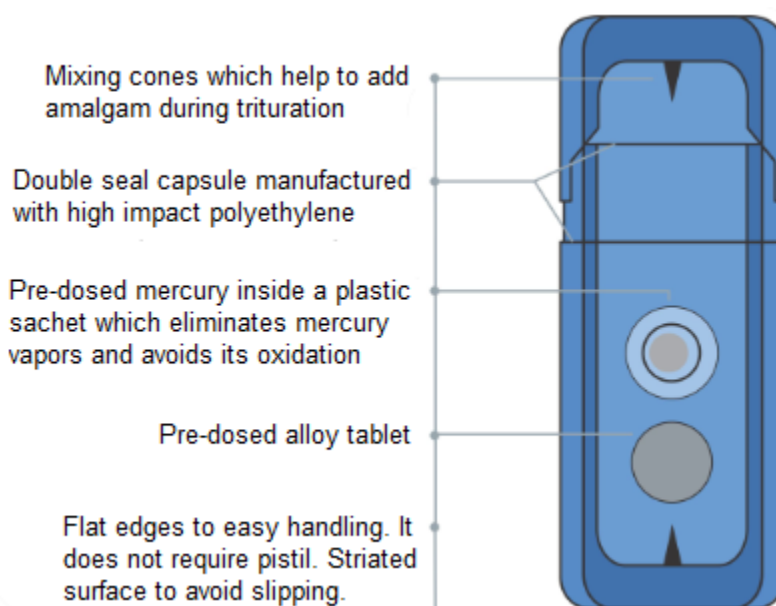


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4. USES AND APPLICATIONS

The amalgam prepared with *High Alloy* is ideal for back teeth morphology and function restoration, when such teeth have lost some of their structure due to injuries caused by cavities or tooth fractures. This procedure can be performed by using self-activating pre-dosed capsules, which have the following features.

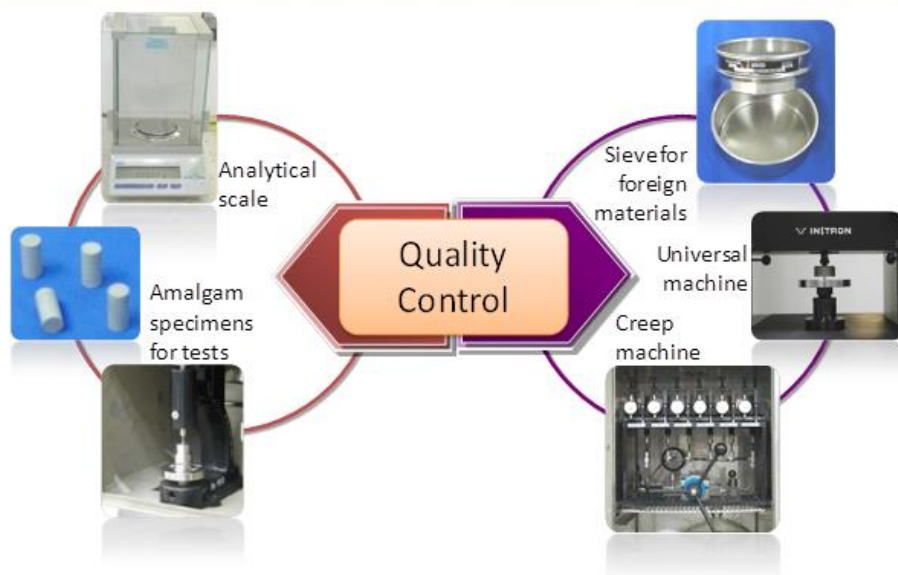


5. QUALITY ASSURANCE OF THE PRODUCT

The product quality is assured starting from the same raw materials which the product is manufactured, for that reason pure metals are used. Also finished product quality is verified in the Quality Control Laboratory under technical standards and with specialized equipment.

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6. INSTRUCTIONS FOR USE

A. Trituration:

Trituration must be performed according to the conditions specified in the instructions for use. Plastic consistency and glossy appearance of the amalgam is an indicator of good trituration conditions. Under trituration (not enough time and/or speed) and over trituration (too much time and/or speed) are detrimental to amalgam properties.

B. Condensation:

Condensation must be made immediately after completing trituration, making enough pressure with each increment in order to ensure proper adaptation of the material to the cavity walls of the tooth. Ultrasonic condensation is not recommended.

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C. Carving and burnishing:



A good morphology guarantees proper occlusion with no contact points which could become later in a fracture. For this, there should be a good marginal adaptation to avoid possible leakage and secondary future cavities.

D. Polishing:

Restoration polishing is very important as it improves the amalgam's surface qualities and protects it against corrosion. A smooth and shiny surface will prevent the adhesion of plaque and will ease cleaning during brushing.

7. COMMERCIAL PRESENTATIONS

Presentations without mercury:

-  Filing x 31.1 g.
-  Tablets x oz.

Pre-dosed capsules:

1, 2 and 3 spill capsules in presentations of 50, 200 and 500 units. Capsule's color indicates spill size, which should be selected according to the size of the cavity to be sealed.



Spill	Capsule Color	Alloy (g)	Mercury (g)
1	Purple (medium size)	0.273	0.300
	Beige (large size)	0.400	0.440
2	White	0.546	0.600
3	Green	0.819	0.900

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8. EXPIRATION DATE

Ten (10) years after its production date.

9. STORAGE AND PRESERVATION CONDITIONS

The product must be kept in its original packaging in order to preserve and prevent it to any possible contamination. It must be placed in a clean, dry and cool place, away from incompatible materials as outlined in the product's Data Sheet.

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