

**TECHNICAL DATA SHEET**  
**NU ALLOY® DP ACTIVE**  
**DPFTPT-015**

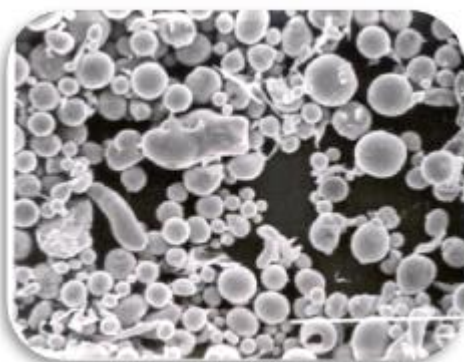
**1. GENERALITIES OF THE PRODUCT**

*Nu Alloy® dp Active* is an admixed particle, high-copper content and zinc-free alloy for dental amalgam, manufactured with specialized equipment in the field of dental metallurgy. Its fine particles ensure a complete reaction with mercury that result in an amalgam with excellent properties. The absence of zinc avoids the secondary or delayed expansion problems which are associated with humidity during dental restoration.

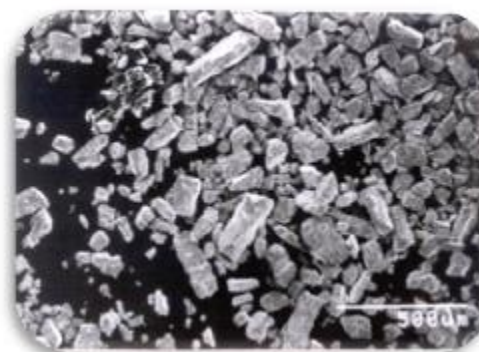
*Nu Alloy® dp Active* is a single composition alloy with homogeneity of its particles. Thanks to its chemical composition (45%Ag, 31%Sn and 24%Cu) and its high copper content, the gamma-2 phase is eliminated from the microstructure of the amalgam. As a result of this, fragility and instability problems in corrosive environments are avoided.

Thanks to both, its morphology which is composed of atomized (spherical) and lathe-cut (prismatic) particles and optimal mercury content (49.6 - 50%, mercury-to-alloy ratio 1/0.98 – 1/1), a fast amalgamation is obtained. It improves the amalgam's physical and mechanical properties.

**Atomized Particles**



**Lathe-Cut Particles**



The period of time necessary for the restoration proceeding is sufficiently comfortable. This allows the use of conventional instruments. The alloy allows obtaining a regular hardening amalgam with a working time of 6 to 8 minutes, however, an amalgam with a shorter working time can be obtained using the product Fast with a working time of 5 to 7 minutes.

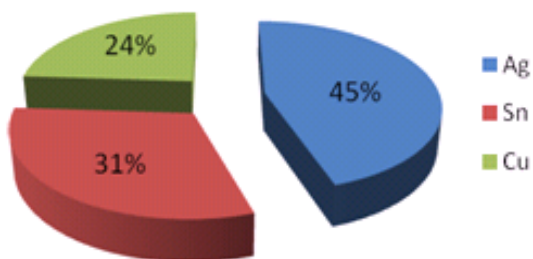
<b>Creation Date</b>		<b>Elaborated by:</b>		<b>Revised by:</b>	
2011-04-19		Technical Analyst of Medical Devices		Technical Coordinator of Medical Devices	
<b>Class</b>	<b>Page</b>	<b>Approved by:</b>		<b>Update:</b>	<b>Version</b>
E	1 of 7	Design and Development Coordinator		2020-04-21	05

**TECHNICAL DATA SHEET  
 NU ALLOY® DP ACTIVE  
 DPFTPT-015**

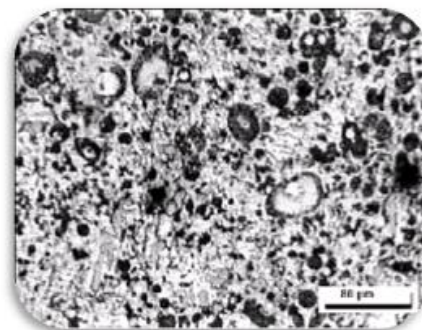
The excellent physical properties of *Nu Alloy® dp Active* ensure a high resistance to marginal fractures, excellent adaptation and marginal sealing, very low corrosion index, and a fine surface finish with lasting shine.

**2. INFORMATION ABOUT COMPOSITION**

Its composition avoids that gamma-2 phase appears in the microstructure of the amalgam. It ensures high mechanical properties.



**Chemical composition of the alloy**



**Metallography**

Metallography in the above photograph shows the typical microstructure of dental alloys. As it is clearly seen, a matrix (white zones) of gamma-1 phase ( $Ag_2Hg_3$ ) - which is the most resistant second phase - surrounds the non-consumed alloy particles (round zones). For their part, these particles are surrounded in their surface by the alloying product with mercury, which is phase  $\eta$  ( $Cu_6Sn_5$ ). The gamma-2 phase ( $Sn_{7-8}Hg$ ) has been avoided.

**3. PROPERTIES OF THE PRODUCT**

According to international standards, the physical properties of *Nu Alloy® dp Active* are measured in the Quality Control Laboratory with specialized gauged equipment. The most relevant physical properties of this product are shown in the following chart.

Creation Date		Elaborated by:		Revised by:	
2011-04-19		Technical Analyst of Medical Devices		Technical Coordinator of Medical Devices	
Class	Page	Approved by:		Update:	Version
E	2 of 7	Design and Development Coordinator		2020-04-21	05

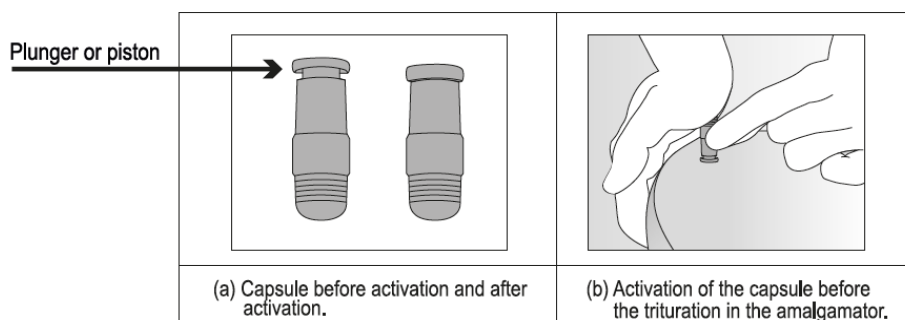
**TECHNICAL DATA SHEET**  
**NU ALLOY® DP ACTIVE**  
**DPFTPT-015**

Property	Standard Requirements (ISO 24234)	Product's Values
Compressive strength after 1 h (MPa)	100 minimum	> 120
Compressive strength after 24 h (MPa)	350 minimum	> 400
Creep (%)	2 maximum	< 0.3
Dimensional change (%)	-0.10 to +0.20	< +0.15
Corrosion resistance	Not apply	Gamma-2 phase-free

#### 4. USES AND APPLICATIONS

Dental amalgam prepared with *Nu Alloy® dp Active* is commonly used as a filling material for restoring the morphology and function of posterior teeth (molars and premolars), mainly in class I-and-II cavities. To do so, the activating capsules system can be used because it offers the following advantages:

- ✓ Capsules are made of high-impact plastic.
- ✓ Mercury is dosed into a hermetic chamber in order to avoid its contamination, oxidation, and escaping of mercury vapors.
- ✓ The base of the capsule has striated surface to allow easy opening of the capsule in order to take out the amalgam.
- ✓ The use of pistil is not needed.
- ✓ The hermetic sealing avoids loss of material during the amalgamation process.
- ✓ There is an immediate amalgamation; it allows using an extensive variety of amalgamators.



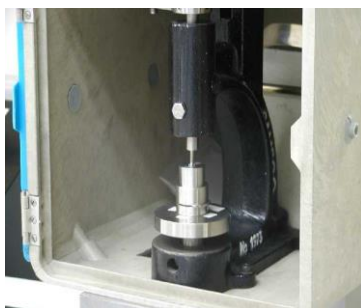
The activation of the capsule can also be made between two fingers.

<b>Creation Date</b>		<b>Elaborated by:</b>		<b>Revised by:</b>	
2011-04-19		Technical Analyst of Medical Devices		Technical Coordinator of Medical Devices	
<b>Class</b>	<b>Page</b>	<b>Approved by:</b>		<b>Update:</b>	<b>Version</b>
E	3 of 7	Design and Development Coordinator		2020-04-21	05

**TECHNICAL DATA SHEET  
 NU ALLOY® DP ACTIVE  
 DPFTPT-015**

**5. QUALITY ASSURANCE OF THE PRODUCT**

*Nu Alloy® dp Active* dental alloy is made of the high-quality raw materials through a completely standardized and certified process which conforms to both ISO 9001 and ISO 13485 for medical devices. Moreover, with the use of specialized equipment in its Quality Control Laboratory, New Stetic continually verifies the fulfilling of quality requisites for the finished product according to ISO 24234.



**Press for the manufacture  
 of test specimens**



**Equipment for creep test**



**Universal Machine for  
 compression strength test**

**6. INSTRUCTIONS FOR USE**

**A. Trituration:**

The activating capsule system is appropriate for an extensive variety of amalgamators. Following chart specifies some equipments extensively used.

Amalgamator	Minimum Trituration Time (s)
Dentomax Compact	12
Ghimas Super Digital	Not advisable
Medimix 3 (max. speed)	12
Promix model 400 (turtle)	20
Promix model 400 (rabbit)	14
Silamat	12
Ultramat 2	12

<b>Creation Date</b>		<b>Elaborated by:</b>		<b>Revised by:</b>	
2011-04-19		Technical Analyst of Medical Devices		Technical Coordinator of Medical Devices	
<b>Class</b>	<b>Page</b>	<b>Approved by:</b>		<b>Update:</b>	<b>Version</b>
E	4 of 7	Design and Development Coordinator		2020-04-21	05



**TECHNICAL DATA SHEET**  
**NU ALLOY® DP ACTIVE**  
**DPFTPT-015**

<b>Amalgamator</b>	<b>Minimum Trituration Time (s)</b>
WIG-L-BUG model LP-60 (med.)	20
WIG-L-BUG model LP-60 (high)	12
YG-SC	25

When using reusable capsules for trituration (kits Duo and Trio), and if the use of a pistil is necessary, use a small pistil for avoiding the overheating of amalgam because this results in dry- and easily-broken amalgams. However, with medium and high-speed amalgamators the use of pistil is not required.

The trituration times shown in the chart can be modified lightly depending on both characteristics of the amalgamator used (age, technical-mechanic condition, line voltage) and the dental professional's preferences.

**B. Condensation:**

Condensation must be carried out as soon as possible after trituration. Use small quantities of product, condensing with each increase until completion of obturation. Remove carefully the mercury-rich layers which can be formed after each condensation, it improves the mechanical properties of the restoration.

**C. Carving and burnishing:**

The excellent characteristics of the product allow, during carving and burnishing, an adequate restoring of the morphology of the dental piece and the adaptation of the amalgam to the marginal edges, in order to avoid filtering and secondary decay later.

**D. Polishing:**

The polishing of the restoration is very important due to it improves the surface qualities of amalgam. A smooth and shining surface improves the corrosion resistance and avoids the adherence of bacterial plaque. Periodical revisions and polishing of the restoration are very important as well, because of it allows that both amalgam recovers its original luster and the restoration stays in best conditions.

<b>Creation Date</b>		<b>Elaborated by:</b>		<b>Revised by:</b>	
2011-04-19		Technical Analyst of Medical Devices		Technical Coordinator of Medical Devices	
<b>Class</b>	<b>Page</b>	<b>Approved by:</b>		<b>Update:</b>	<b>Version</b>
E	5 of 7	Design and Development Coordinator		2020-04-21	05



**TECHNICAL DATA SHEET**  
**NU ALLOY® DP ACTIVE**  
**DPFTPT-015**

**7. COMMERCIAL PRESENTATIONS OF PRODUCT**

**Presentations without mercury:**

- Powder: Bottle x 30 g.
- Tablets: Box x 1 oz (80 one-spill tablets).

**Pre-dosed activating capsules:**

- Bottle x 50, 100, 200, and 500 units of 1, 2, and 3 spill.

Spill	Regular hardening			Fast hardening		
	Capsule color	Alloy (g)	Mercury (g)	Capsule color	Alloy (g)	Mercury (g)
1	White/White	0.395	0.388	White/Maroon	0.395	0.350
2	White/Violet	0.531	0.522	White/Green	0.531	0.471
3	White/Orange	0.790	0.776	White/Blue	0.790	0.700
Alloy/Hg ratio: 1/0.98 (49.6% Hg)			Alloy/Hg ratio: 1/0.89 (47.0% Hg)			



**Kits:**

- Duo: Box x 80 tablets of 1 spill + 80 mercury sachets + 1 reusable capsule.
- Trio: Box x 240 tablets of 1 spill + 240 mercury sachets + 4 reusable capsules.

**8. EXPIRATION DATE**

Ten (10) years after its manufacturing date.

<b>Creation Date</b>		<b>Elaborated by:</b>		<b>Revised by:</b>	
2011-04-19		Technical Analyst of Medical Devices		Technical Coordinator of Medical Devices	
<b>Class</b>	<b>Page</b>	<b>Approved by:</b>		<b>Update:</b>	<b>Version</b>
E	6 of 7	Design and Development Coordinator		2020-04-21	05



Address: Cra. 53 N° 50-09  
Guarne (Antioquia) COLOMBIA.  
Telephone: (574) 550 00 00  
Fax: (574) 551 31 34

**TECHNICAL DATA SHEET  
NU ALLOY® DP ACTIVE  
DPFTPT-015**

**9. STORAGE AND PRESERVATION CONDITIONS**

This product must be kept in its original packing in order to protect it from possible contamination. It must be placed in a dry, cool, and clean area, away from both heat sources and direct sunlight.

For presentations with tablets, avoid excessive manipulation of product or its continuous agitation because it can cause loss of alloy from the tablets and consequently the mercury-to-alloy ratio is altered. Equally, avoid taking out all tablets at the same time because this will produce the same negative effect.

<b>Creation Date</b>		<b>Elaborated by:</b>		<b>Revised by:</b>	
2011-04-19		Technical Analyst of Medical Devices		Technical Coordinator of Medical Devices	
<b>Class</b>	<b>Page</b>	<b>Approved by:</b>		<b>Update:</b>	<b>Version</b>
E	7 of 7	Design and Development Coordinator		2020-04-21	05

REFERENCE DOCUMENT: DPDDPR-019  
UPDATE: 2017-12-02  
VERSION: 00