

**TECHNICAL DATA SHEET
 ACRYLIC RESIN TEETH
 DPFTPT-004**

1. GENERALITIES OF THE PRODUCT

Teeth are structures implanted in maxillary bones of vertebrates. They are made to grasp and chew food while adding functionality and aesthetics to the oral cavity. In this way, acrylic resin teeth satisfy the two basic requirements of natural teeth, functionality and aesthetics, when they are totally or partially restored, or as fixed pieces in the case of provisional crowns.

Teeth are classified into two classes: Class I corresponds to front teeth that go from one canine to the other canine; Class II corresponds to both upper and lower teeth that go from the first premolar to the second molar.

Back teeth may vary in their occlusion surfaces, as follows:

Molars with inverted cusps (0 degrees): These teeth have no cusps or prominences on the chewing surfaces. Their occlusion surfaces are not exact copies of natural forms, but their design allows to re-establish and satisfy the functionality needs of the chewing process as well as patient's phonation needs. Functionality consideration is specially recommended for aged people.

Semi-anatomic molars (10 and 20 degrees): These teeth have a narrow buccolingual dimension. They offer an intermediate alternative in aesthetics and functionality between anatomic molars and molars with inverted cusps (0 degrees).

Anatomic molars (33 degrees): These artificial teeth are very similar in their anatomy to non-worn natural teeth. They have been designed for complete dentures in young patients. These teeth reduce the chewing pressure in the supporting area of the denture because the depth of the basins and the height of cusps allow a much more efficient and physiological chewing.

Four-layered back teeth may vary according to the type of articulation of their occlusion surfaces, as follows:

Normal articulation: In normal articulation, the profile analysis of the vertical arc of front teeth shows an inter-vestibular joint line which is perpendicular to the occlusion plane.

Creation date		Elaborated by:		Revised by:	
2010-01-06		Technical Analyst of Medical Devices		Analyst of Dental Pieces Design	
Class	Page	Approved by:		Update:	Version
E	1 of 6	Technical Director of Medical Devices		2019-06-16	07

**TECHNICAL DATA SHEET
 ACRYLIC RESIN TEETH
 DPFTPT-004**

Crossed articulation: In crossed articulation, the profile shows a protruded jaw. The inter-vestibular joint line forms a relatively small angle in relation to the occlusion plane.

2. INFORMATION ABOUT COMPOSITION

Polymethyl Methacrylate
 Cross Link (Ethylene glycol dimethacrylate)
 Fluorescence
 Pigments

3. PHYSICAL PROPERTIES

Physical properties of acrylic resin teeth are verified in New Stetic's Quality Control Laboratory by means of well-gauged and highly specialized equipment, according to ISO Standard 22112. Dentistry – Artificial teeth for dental prostheses.

The most relevant physical properties of our acrylic resin teeth are as follows:

Surface finish: When prosthesis has been made through the conventional heat-polymerized or microwave-polymerized methods, artificial teeth can recuperate the gloss they initially had in the demonstration item by applying abrasion to the teeth surface.

Bonding to the denture base: Acrylic resin teeth and denture base resin Opticryl® have a chemical bonding.

Dimensional stability: Dimensional stability is the tooth's resistance to contraction or expansion during the making of prosthesis, when subjected to the temperature changes of the polymerization process. Dimensional changes of teeth must not exceed $\pm 2.0\%$.

Comparison with the color guide: The central upper left tooth of front-teeth sets must match with the color guide furnished by the manufacturer.

Inspection and conformity with the mold chart: Dimensions of acrylic resin teeth compared with the mold chart values must not exceed $\pm 5\%$.

Creation date		Elaborated by:	Revised by:	
2010-01-06		Technical Analyst of Medical Devices	Analyst of Dental Pieces Design	
Class	Page	Approved by:	Update:	Version
E	2 of 6	Technical Director of Medical Devices	2019-06-16	07

**TECHNICAL DATA SHEET
 ACRYLIC RESIN TEETH
 DPFTPT-004**

Resistance to whitening, distortion, or crazing: When denture teeth have been subjected to temperature changes and then immersed in a monomer solution, teeth must not show any whitening, distortion or crazing in the stereomicroscope.

Porosity and other defects: Acrylic teeth must not show porous or any other defect in a cutaway view in the stereomicroscope, if image is increased 10 times.

Fluorescence: Acrylic resin teeth must be fluorescent.

4. USES AND APPLICATIONS

Acrylic resin teeth are structures intended to replace the loss of one or several dental pieces.

Acrylic teeth come in a wide variety of tooth shades and forms that can be adapted to each patient's physiognomy. New Stetic's acrylic teeth are classified into lines according to their layered structures: Two-layer acrylic teeth, Three-layer acrylic teeth, and Four-layer acrylic teeth.

All these lines have the following features:

- Wider variety of form and color references.
- Molds used to manufacture our acrylic teeth ensure an excellent reproduction of the morphology and anatomy of natural teeth. This feature allows a reproduction of patient's dental occlusion according to his/her previous diagnostic.
- Wide variety of articulations in back teeth such as 0°, 10°, 20°, and 33°. Normal and crossed articulations satisfy the needs of patients with retrognathism, prognathism, or normal chewing.
- Exceptional hardness, durability, and functionality.
- Their morphology and mixture of multiple color layers give them a natural appearance.
- They are biocompatible with oral tissues.
- Shades and translucent tonalities that give their vitality to artificial teeth used in dental - restorations are exactly reproduced.
- Color in front and back teeth is exactly reproduced.
- 4-layered acrylic teeth have darker necks that contrast with their body, as it happens with a natural tooth whose root is darker than its crown.

Creation date		Elaborated by:		Revised by:	
2010-01-06		Technical Analyst of Medical Devices		Analyst of Dental Pieces Design	
Class	Page	Approved by:		Update:	Version
E	3 of 6	Technical Director of Medical Devices		2019-06-16	07

**TECHNICAL DATA SHEET
 ACRYLIC RESIN TEETH
 DPFTPT-004**

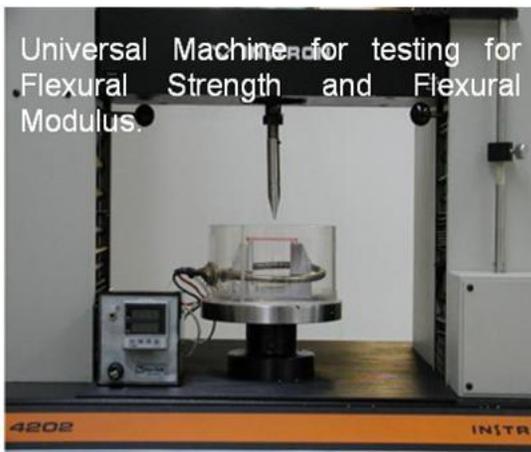
- Their chemical composition ensures a physical and chemical bonding to the denture base.
- Acrylic resin teeth are very easily adaptable.
- They are highly resistant to breakage.
- Their capacity to bond to heat-polymerized resins for denture bases allows a longer life-time of prosthesis in patient's mouth.
- Acrylic resin teeth are made to restore patient's functionality and aesthetics.

5. QUALITY ASSURANCE OF THE PRODUCT

Acrylic resin teeth are made from the highest quality raw materials through a completely standardized process which conforms to ISO Standard 9001 and ISO 13485.

Moreover, in its Quality Control Laboratory, New Stetic verifies the fulfilling of quality requisites for its finished product Acrylic Resin Teeth, using specialized equipment.

The most representative machines are the following:



Creation date		Elaborated by:	Revised by:	
2010-01-06		Technical Analyst of Medical Devices	Analyst of Dental Pieces Design	
Class	Page	Approved by:	Update:	Version
E	4 of 6	Technical Director of Medical Devices	2019-06-16	07

**TECHNICAL DATA SHEET
 ACRYLIC RESIN TEETH
 DPFTPT-004**



6. INSTRUCTIONS FOR USE

After the lining-up of teeth and the wax washing, the following recommendations must be taken into account before putting the acrylic resin:

Carry out a traditional wax washing operation, in order to completely remove the wax that is adhered to teeth.

Teeth must be completely clean at the moment of putting the denture base resin. The presence of detergent waste impedes the chemical bonding between the tooth and the denture base resin.

When applying the plaster separator (Novafoil), acrylic resin teeth must never be touched in order to ensure their bonding.

Acrylic resin teeth (Polymethyl Methacrylate) must be worked with denture base acrylic resin of equal component, in order to ensure their chemical bonding (with no need of mechanical retentions by means of diatoric holes). Mechanical retentions should be avoided because they affect the tonality of artificial teeth.

Do not immerse teeth in solvents because it affects the physical features of teeth and produces micro-fractures not detectable at first sight but through a stereomicroscope.

Creation date		Elaborated by:	Revised by:	
2010-01-06		Technical Analyst of Medical Devices	Analyst of Dental Pieces Design	
Class	Page	Approved by:	Update:	Version
E	5 of 6	Technical Director of Medical Devices	2019-06-16	07

**TECHNICAL DATA SHEET
 ACRYLIC RESIN TEETH
 DPFTPT-004**

7. COMMERCIAL PRESENTATIONS

- Box X 20 sets (Each set X 6 pieces type I)
- Box X 20 sets (Each set X 8 pieces type II)
- Box X 12 sets (Each set X 14 pieces = 6 pieces type I + 8 pieces type II)
- Box X 10 sets (Each set X 6 pieces type I)
- Box X 10 sets (Each set X 8 pieces type II)
- Box X 6 sets (Each set X 28 pieces = 12 pieces type I + 16 pieces type II)
- Plastic bag per 10 sets type I; type II
- Individual presentation, set x 6 pieces type I
- Individual presentation, set x 8 pieces type II
- Individual presentation, set x 14 pieces = 6 pieces type I + 8 pieces type II
- Individual presentation, set x 28 pieces= 12 pieces type I + 16 pieces type II

Two-layer Acrylic Teeth Line: Newcryn, Coral, Splendid, Ultradent, Nordent, Biodent, T-Real, Olympic, Alfalux, Super C, Superdent, New Shade Plus, Dual Form V, Olympic® Plus.

Three-layer Acrylic Teeth Line: Tiziano, Image APN, Entacryl.

Four-layer Acrylic Teeth Line: Duratone-n; Stein Vit®; Reflection; GoodFit

8. EXPIRATION DATE

Ten (10) years, according to stability study.

The useful life of 10 years device time, however, the artificial teeth are highly stable in time; since they are made out of a totally polymerized material; even for periods longer than ten years used in this study. The ten-year period statement has commercial implications; given that a period of time during which the organization will provide a support service to the product mentioned above must be established.

9. STORAGE AND PRESERVATION CONDITIONS

Acrylic resin teeth must be stored in a cool and dry place, at a temperature lower than 40°C.

Creation date		Elaborated by:		Revised by:	
2010-01-06		Technical Analyst of Medical Devices		Analyst of Dental Pieces Design	
Class	Page	Approved by:		Update:	Version
E	6 of 6	Technical Director of Medical Devices		2019-06-16	07