

# Technical Data and Clinical Overview

## Technical Data

Eclipse is a visible light polymerizable system that utilizes three resins layered together to fabricate a denture (i.e., Base Plate, Set-Up and Contour Resins). Denture fabrication is streamlined since the lost wax technique is not required and there is no need for investing, flasking and boilout. The cured denture/nightguard materials' aesthetics are as good as, or better than that obtained with conventional acrylic devices and exhibit excellent mechanical properties. For complete dentures, the baseplate used for the occlusal rims becomes part of the final denture, providing a superior fit of the final denture.

Eclipse is composed of urethane oligomers, a class of materials which has found wide acceptance in various dental applications and is free of methyl, ethyl, propyl or butyl monomers. Eclipse's uniquely formulated resins surpass the physical and mechanical properties of earlier urethane materials.

*The performance of these materials is described in terms of several in-vitro tests, as follows:*

### 1. Safety

Eclipse materials have been thoroughly tested and comply with FDA requirements, ISO 10993 guidelines and International Standard ISO 7045. The toxicological/biocompatibility test matrix includes cytotoxicity, genotoxicity (Ames), sensitization, irritation and oral toxicity evaluations.

### 2. ADA and ISO specifications

All four Eclipse materials, including Baseplate, Clear Baseplate, Set-UP and Contour Resins, and associated shades comply with ADA 12 and ISO 1567 specifications. Mechanical retention of teeth is required.

### 3. Denture Fit

The "fit" of Eclipse appliances has been assessed and verified as follows. First, as defined by a measured gap between the device and the parent model; second, in terms of Certified Dental Technician evaluation of adaptation to the model; third, via an articulation study; and, finally, by clinical observation of fit of the denture at delivery versus at try-in (100 + appliances). Clinically, the fit of Eclipse dentures at delivery has been excellent, equaling or surpassing that achieved by the conventional lost wax/acrylic denture process. Fit of the denture at try-in has been clinically shown to equal fit of the completed appliance at delivery and is a major improvement in denture fabrication and in addressing patients' needs.

**Gap:** Measurements were taken between the denture and the stone at the posterior border of upper and lower dentures using a measuring microscope.

Type	Gap Upper (mm)	Gap Lower (mm)
Eclipse	0.64	0.30
Acrylic	0.77	0.45

**CDT Evaluation:** In all reviewed cases, visual assessment of fit was found to be acceptable by internal evaluators. This assessment was performed at three specific steps: After baseplate fabrication, but prior to removal from the model; after wax rim removal and reseating onto the model; and, finally, immediately prior to delivery.

**Articulation Study:** Articulation was acceptable both prior to and post-polymerization / curing. As observed by internal technicians, the pin opening is typically smaller for Eclipse appliances than traditional acrylic cases and implies less accumulated process error in comparison with the pack technique.

**Clinical Observation:** Clinician and patient responses indicate that a superior fit of the final denture can be made.

### 4. Tooth Retention

Mechanical retention is required to retain denture teeth in devices fabricated from Eclipse resin. Keyed slot retention and/or collar groove are the two methods of choice for effective tooth retention. Eclipse provides retention strength similar to that of pour acrylic resins and complies with ISO 1567 tooth retention requirements (per internal evaluation).

### 5. Shrinkage

Volumetric polymerization shrinkage is less than that of heat-cured acrylics. Shrinkage of the individual Eclipse resins comprising the devices is at least 50% less than that of heat-cured acrylic.

Material	% Polymerization Shrinkage (Volumetric)
Eclipse Base Plate Resin	3.2
Eclipse Set-Up Resin	2.6
Eclipse Contour Resin	2.0
Lucitone 199 <sup>®</sup>	7.0

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## 6. Flexural Properties

Eclipse resins and the layered materials provide excellent flexural properties compared to commercially available and clinically effective materials. These findings have been confirmed by independent laboratory testing.

### Flexural Strength of Eclipse vs. conventional Acrylics

Material	Flexural Strength MPa	Flexural Modulus GPa
Eclipse Clear Base Plate Resin	123	3.3
Eclipse Base Plate Resin	125	3.2
Eclipse Set-Up Resin	123	3.1
Eclipse Contour Resin	113	2.9
Lucitone 199®	95	2.8
Selectaplus	63	2.4
Selectaplus H	74	2.6

## 7. Impact Strength

Eclipse resins by themselves, as well as layered Eclipse resins, provide excellent impact properties compared to commercially available, clinically effective acrylic materials. These findings have been confirmed by independent laboratory testing.

### Impact Strength of Eclipse vs. Acrylics

Material	Un-notched impact strength kJ/m <sup>2</sup>
Eclipse Clear Resin	16.8
Eclipse Base Plate Resin	14.7
Eclipse Set-Up Resin	11.3
Eclipse Contour Resin	7.3
Eclipse Base Plate-Base Plate	16.3
Eclipse Base Plate-Contour	9.6
Lucitone 199®	9.8
Selectaplus	1.9
Selectaplus H	2.3

## 8. Appliance Design

An Eclipse appliance is essentially comprised of a layering of three materials: Base Plate, Set-Up and Contour Resin. As might be expected, the interface between the respective materials is critical in determining performance of a device constructed in this manner. Flexural properties of layered test specimens are consistent with the properties of the component materials and compare favorably with common dental resins. Moreover, extended hydrolytic testing (immersion

in water) at elevated temperatures indicates that the layered materials are stable, with no indication of delamination prior to or after destructive testing. Repairs are similarly stable and effective.

### Flexural Properties – Layered Eclipse

Material Combination	Flexural Strength MPa	Deflection mm	Flexural Modulus GPa
Eclipse Base Plate/Contour	123	9.4	3.3
Eclipse Base Plate/Base Plate	125	9.1	3.2

## 9. Hydrolytic Stability

Hydrolytic testing shows that the flexural properties of Eclipse resins are effectively maintained upon extended periods of immersion in water at elevated temperatures.

### Flexural Properties of Hydrated Eclipse

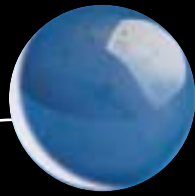
Material	Water Immersion Period	Flexural Strength MPa	Deflection mm	Flexural Modulus GPa
Eclipse Base Plate Resin	Baseline	120	9.1	3.2
	Hydrated for 15 mths at 37°	132	9.4	3.3
Eclipse Contour Resin	Baseline	118	8.9	3.0
	Hydrated for 15 mths at 37°	125	9.1	3.2
Lucitone 199®	Baseline	97	9.7	2.9
	Hydrated for 15 mths at 37°	99	9.7	2.9

### Flexural Properties of Layered Hydrated Eclipse Repairs

Material	Water Immersion Period	Flexural Strength MPa	Deflection mm	Flexural Modulus GPa
Base Plate/Contour	Baseline	123	9.4	3.3
	Hydrated for 12 mths at 37°	130	9.1	3.3
Base Plate/Base Plate	Baseline	125	9.1	3.2
	Hydrated for 12 mths at 37°	139	9.1	3.4

### Flexural Properties of Hydrated Eclipse Repairs

Material	Water Immersion Period	Flexural Strength MPa	Deflection mm	Flexural Modulus GPa
Base Plate/Base Plate Repair	Baseline	117	9.7	3.1
	Hydrated for 6 mths at 37°	131	8.6	3.4



## 10. Color Stability

All four Eclipse materials, including Base Plate, Clear Base Plate, Set-Up and Contour Resins, comply with the UV color stability requirements of the ADA 12 and ISO 1567 standards. Eclipse shade variants are also color stable.

## 11. Stain Resistance

The Eclipse chemistry is inherently resistant to common staining chromophores that are consumed during eating and drinking. Good stain resistance was demonstrated with two common staining agents, coffee and mustard, in an internal accelerated in-vitro stain test when appliances were properly polished. It is important to achieve a smooth surface when polishing the appliances since rough, unpolished areas may show slight stain, similar to conventional denture base materials.

In-vitro mustard stain resistance is similar to Lucitone 199 denture base material. Dentures, repairs and relines all show acceptable stain resistance.

## 12. Plaque Resistance

Some Eclipse clinical case reviews from the clinical study have shown that plaque growth on devices appears to be equal to or better than that of a typical acrylic appliance.

## 13. Working Time

Eclipse materials are designed to be light polymerized in a processing unit developed for this purpose. Accordingly, these materials are also sensitive to ambient light but have a minimum "working time" of 60 minutes under typical room illumination. You must avoid exposing Eclipse materials to direct sunlight prior to processing.

## 14. Shelf Life

All uncured Eclipse resins have a shelf life of two years when stored at room temperature in light-safe conditions away from direct sunlight.

## Clinical Overview



A multi-site clinical study was conducted to assess fit, function, color stability, tissue compatibility, and overall patient acceptance of Eclipse dentures, removable partial dentures and occlusal splints.

This study evaluated complete dentures, partial dentures, and occlusal splints in 145 patients as of August 2002, with some restorations/appliances now over two years old. This investigation evaluated Eclipse appliances for fit, soft tissue compatibility, resistance to breakage, tooth retention, as well as patient acceptance, including aesthetic, feel, taste and hygiene perceptions.

### Data Collected

The following data were collected for Full Dentures:

- Tissue inflammation (DePaola Index)
- Denture base fit and stability at try-in, insertion and recalls (modified Kapur Index)
- Ease of tooth position adjustment (if needed)
- Tissue reaction to unprocessed denture base material
- Color stability at recalls
- Evidence of allergic reaction at recalls
- Other observations (debonds, textural changes, etc.)

The following data were collected for Partial Dentures:

- Tissue inflammation (DePaola Index)
- Ease of tooth position adjustment (if needed)
- Tissue reaction to unprocessed denture base material
- Color stability at recalls
- Evidence of allergic reaction at recalls
- Other observations (debonds, textural changes, etc.)

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For full and partial dentures, patients were asked about taste and odour from the appliance at try-in and at recalls.

Additionally, they were asked about:

- Overall satisfaction with the appliance
- Ease of maintenance (cleaning)
- Aesthetics
- Overall acceptability

For occlusal splints, the following data were collected:

- Incidence of breakage
- Color stability
- Evidence of excessive wear
- Taste
- Odour

## Summary of Findings:

The truly remarkable results of this continuing clinical study substantiate the clinical claims that a superior fitting denture can be made and that elimination of methylmethacrylate monomer results in a non-irritating, functional, aesthetic, durable, hygienic prosthesis without objectionable taste or odour.

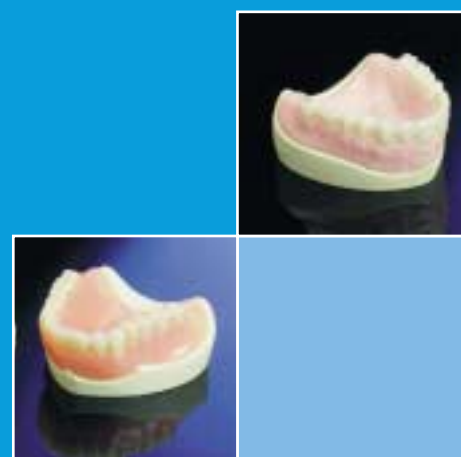
- No evidence of any allergic reaction has been noted.
- The material appears kind of the mucosal tissues.
- Reaction of the tissue to the uncured materials is benign.
- Denture base fit as assessed with the Modified Kapur Index is excellent.
- Few changes were observed between try-in, insertion and recall visits.
- The processed baseplate yields exceptional stability and retention at try-in, accurately predicting fit and stability at insertion.
- The denture base material is color-stable.
- Occlusal splints are successful.

## In Conclusion

We believe that Eclipse is a breakthrough in prosthetic resin technology. It is essentially a material that handles like wax and polymerizes to the standards of a conventional denture base material. Based on initial observations from our multi-site clinical study, with some patients having worn their Eclipse dentures for well over two years, we are confident that an Eclipse processed baseplate offers a superior fitting denture.\*

Eclipse is a clear advantage over conventional dentures because now problems with fit can be caught early in the treatment process.

\* Monitoring of clinical cases will continue through two-year patient recalls.



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