



# Enigma Composite Stains Instructions for Use

#### 1. INTENDED PURPOSE

Enigma Composite Stains are composite-based colours that are used to individualize or characterize a wide variety of dental materials.

# 2. DESCRIPTION OF PRODUCT & USERS 2.1 Product description

Enigma Composite Stains are light-curing stains for crown and bridge techniques that are suitable for use with composite veneers or denture acrylics.

#### 2.2 Users

For use by laboratory technicians in a dental laboratory.

#### 3. COMPOSITION, SHADES & PRODUCT CODES

Di-urethane dimethacrylate, tetramethylene dimethacrylate, silicon dioxide, glass powder, pigments, initiators, Fillers: 48 wt.% inorganic filling materials (0.005-3.0 µm)

 Intense Red
 REF
 0350-R

 Intense Blue
 REF
 0350-B

 Light Brown
 REF
 0350-LB

 Dark Brown
 REF
 0350-DB

#### 4. INDICATIONS

Characterisation of composite veneers using crown and bridge techniques. Customisation of prefabricated acrylic teeth. Characterisation of base acrylics in partial or complete dentures.

#### 5. CONTRAINDICATIONS

Do not use in the case of a known allergy to one of the components.

# 6. WARNINGS

Warning! Contains di-urethane dimethacrylate, tetramethylene dimethacrylate, diphenyl (2,4,6-trimethylbenzoyl) phosphine oxide. May cause an allergic skin reaction.

### 7. PRECAUTIONARY INSTRUCTIONS

Avoid breathing vapour or spray. Wear protective gloves. If skin irritation or rash occurs: Get medical advice/ attention

### 8. INTERACTIONS WITH OTHER AGENTS

Phenolic substances such as Eugenol inhibit polymerisation. Therefore, do not use any material containing these substances.

#### 9. APPLICATION / PREPARATION

Processing times: 1-3 minutes, depending on lighting conditions.

# 9.1 Characterisation of composite veneers using crown & bridge techniques

#### 9.1.1 Insertion between composite paste layers

The composite used is applied as usual (follow manufacturer's instructions). The stains can be applied between the individual layers for customisation purposes. The stains are expressed from the syringe onto a palette and applied as required using a brush. The composite is re-applied following interim polymerisation.

#### 9.1.2 Surface Painting technique

If the composite veneer is already prepared, the surface must be roughened first and a new dispersion layer created using a bonding/primer fluid for composites (follow manufacturer's instructions). The stains can then be applied to these as required. This is followed by final polymerisation.

#### 9.2 Customisation of prefabricated acrylic teeth

The surface must be roughened first using a tungsten carbide bur and a new dispersion layer created using a bonding/primer fluid for composites (follow manufacturer's instructions). The stains can then be applied to these as required. This is followed by final polymerisation.

# 9.3 Characterisation of base acrylics in partial or complete dentures

The surface must be roughened first using a tungsten carbide bur and a new dispersion layer created using a bonding/primer fluid for composites (follow manufacturer's instructions). The stains can then be applied to these as required. This is followed by final polymerisation.

### 9.4 Finishing

Polishing is performed with goat bristle brushes, polishing paste and soft cotton wool discs. Careful surface finishing and polishing is essential for an optimal result and largely prevents the formation of deposits (nicotine, caffeine etc.) as well as the discolouration associated with this.

#### 10. POLYMERISATION TIMES

Light-curing unit	Interim polymerisation	Final polymerisation
Spektra LED	30 seconds	1 minute
Spektra 2000	1 minute	3 minutes
HiLite / UniXS	90 seconds	3 minutes
Labolight LV-II / III	1 minute	5 minutes
Solidilite	1 minute	5 minutes

#### 11. TROUBLESHOOTING / FAQ LIST

Remove any layers of grease and polishing waste from the frame surfaces.

Fault	Cause	Corrective action
Stain peels off	Insufficient bond to the surface to which applied	Surfaces must be roughened and a bonding/primer fluid applied
Voids during insertion between composite layers		Do not mix individual layers
Surface greasy or sticky	Inadequate polymerisation	Observe the polymerisation times Check curing unit and service regularly

#### 12. STORAGE & HANDLING INFORMATION

Storage temperature 10-25°C / 50-77°F. Close syringe carefully.

#### 13. SHELF LIFE

The maximum shelf life is printed on the label of each pack. Do not use after the expiry date.

# 14. WARNINGS ON SIDE EFFECTS

With proper preparation and use of this medical device, adverse effects are extremely rare.

However, immune reactions (such as allergies) or local discomfort cannot in principle be ruled out completely. All serious incidents which occur in connection with the use of this product are to be reported to the manufacturer indicated below and the competent authority in each case.

### 15. INSTRUCTIONS FOR DISPOSAL

Leftover quantities and packaging materials are to be disposed of according to the local and/or statutory regulations.

