EcuSeal

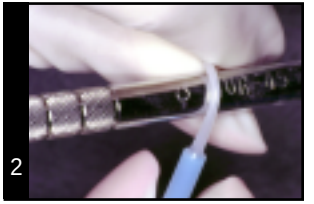
DESCRIPTION

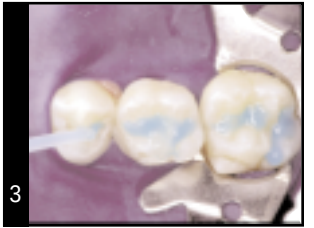
EcuSeal is a light curing pit and fissure sealant containing an ionomer glass with zinc and fluoride. The introductory kit includes unit dosed Mikro-tip carpules of both EcuSeal and Ecusit Etch which are designed for quadrant preventative dentistry. Also included in the introductory kit are 2 "Ecu-PENs" which feature a unique rolling mechanism at the operators index finger to allow for easy, smooth, and accurate placement of both EcuSeal and Ecusit Etch.

DMG HAMBURG

US PAT. 4,872,936
European PAT. 0 219 058

CE 0482





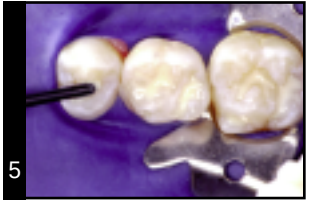
INSTRUCTIONS

1 Isolate all surfaces to be sealed; for best results maintain a dry field.
Use of a rubber dam is recommended.

2 Clean all surfaces to be sealed: a) Rinse with an oil free water spray and dry OR b) Apply a suitable cleansing agent to the surfaces, then rinse with water spray and dry.
NOTE: Cleansing of the tooth surfaces may also be accomplished with any type of air abrasion device.

3 Insert the transparent Mikro-tip of etch gel into the blue handled Ecu-PEN (**Fig 1**). To slide the Mikro-tip into place; black plunger must be flush with Ecu-PEN opening. NOTE: Before insertion into the Ecu-PEN gently bend Ecusit Etch Mikro-tip at midpoint around the handle of a dental instrument to facilitate application of Ecusit Etch (**Fig 2**).

4 Place the tip of the Ecusit Etch Mikro-tip at the most distal end of the most distal tooth to be sealed. Moving towards the mesial dispense the Ecusit Etch by sliding the operator's index finger on the roller mechanism in the same direction in which the Ecu-PEN is moving (**Fig 3**). Cover all surfaces in one continuous motion.



5 Allow Ecusit Etch to remain on the surface for 15 to 30 seconds.

6 Rinse off the Ecusit Etch with a water spray and dry. The enamel should have a "frosted" appearance.

If "frosted" appearance is not noted, repeat steps **4**, **5** and **6**.

7 Insert the black Mikro-tip of EcuSeal into the off-white handled Ecu-PEN (**Fig 4**). To slide the Mikro-Tip into place, black plunger must be flush with Ecu-PEN opening. NOTE: Before insertion into the Ecu-PEN gently bend EcuSeal Mikro-Tip at midpoint around the handle of a dental instrument to facilitate easy application of EcuSeal (**Fig 2**).

8 Place the tip of the EcuSeal Mikro-Tip at the most distal end of the most distal tooth to be sealed. Moving towards the mesial dispense the EcuSeal by sliding the operator's index finger on the roller mechanism in the same direction in which the Ecu-PEN is moving. Cover all surfaces in one continuous motion (**Fig 5**). Excess material should be removed with a brush.

9 Light cure each tooth for 40 seconds. Check for smoothness with a probe. NOTE: Surface may be sticky due to formation of air inhibited layer. Use ethanol to remove this film.

10 Remove rubber dam (**Fig 6**). Check occlusion, adjusting if necessary. (**See Helpful Hints**). Repeat on next quadrant.

RE APPLICATION

Sealant should be checked periodically. If sealant is completely missing, repeat total etching and coating process. Additional sealant may be added to the bonded material by abrading surface of the sealant present and adding new material.

HELPFUL HINTS

- If occlusal adjustments are indicated use a 30 fluted carbide bur or fine diamond bur followed with either a composite or polishing paste applied with a prophy cup.
- Always place EcuSeal in the off-white handled Ecu-PEN and the Ecusit Etch in the blue handled Ecu-PEN to eliminate any confusion when sealing multiple quadrants.

PRECAUTIONS

- Do not take internally.
- Ecusit Etch contains 37% phosphoric acid. Avoid contact with soft tissue.
- In case of contact with skin or eyes, wash immediately with water.
  Get medical attention for eyes.
- Store in a cool, dry place away from direct sunlight.

INDICATIONS

- For use as a caries preventative restoration on both primary and permanent dentition where there is a potential risk of caries.
- Buccal and lingual grooves may be treated when clear of gingiva.

CONTRA INDICATIONS

- The sealing of pits and fissures using enamel etching technique is contra-indicated when caries is already present in the pits and fissures, and where it is difficult to keep the area dry during the application and curing of the sealant.
- Sealant should not be used when known allergies to the components of the etch or sealant exist.
- In some cases individual contact allergies may exist.
- Sealant should not be used on a patient who does not cooperate in maintaining good oral hygiene.
- Sealant should not be used on occlusal surfaces where pits and fissures do not exist.
- Sealant should not be used on teeth free of caries for a number of years, or on teeth with many proximal lesions.

STERILIZATION AND INFECTION CONTROL

- All tips are for one time use.
- Ecu-PEN is autoclavable up to 130 °C. It will withstand 100 autoclave cycles.

COMPOSITION

EcuSeal: Bis-GMA, polymethacrylated carbonic acids, ionomer glass, catalysts, triethyleneglycol dimethyacrylate (TEDMA), silica

Ecusit Etch: Water, phosphoric acid, aerosil

CONTENTS

INTRODUCTORY KIT

50 Mikro-tips EcuSeal (black tips)
50 Mikro-tips Ecusit Etch (clear tips filled with blue etch)
1 off white handled Ecu-PEN applicator (for application of EcuSeal)
1 blue handled Ecu-PEN applicator (for application of Ecusit Etch)
(The kit contains sufficient material to seal up to 200 occlusal surfaces)

EcuSeal REFILL

50 Mikro-tips EcuSeal (black tips)

Ecusit Etch REFILL

50 Mikro-tips Etch Gel (clear tips filled with blue etch)

Ecu-PENs can also be purchased separately.

Federal Law restricts this device to sale by, or on the order of a dentist, or other practitioner licensed by the law of the state in which he or she practices to use or order the use of this device

For questions or comments in the USA , please call

Zenith at 1-800-662-6383

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

ZENITH DMG Enhancing Dentistry with Education and Technology®

Manufactured by: DMG CPF Hamburg
Exclusively Distributed in the United States and Canada by:
Zenith Brands Division of Foremost Dental Mfg. Co., Inc.
Telephone number: 1-800-662-6383

Material Safety Data Sheet

May be used to comply with OSHA's Hazard Communication Standard, 29 CFR 1910.1200. Standard must be consulted for specific requirements.

U.S. Department of Labor
Occupational Safety and Health Administration
(Non-Mandatory Form)
Form Approved
OMB No. 1218-0072

IDENTITY (As Used on Label and List): EcuSeal

Note: Blank spaces are not permitted. If any item is not applicable, or no information is available, the space must be marked to indicate that.

Section I

Manufacturer's Name: DMG

Address (Number, Street, City, State, and Zip Code): Eltbgaustrabe 248, 22547 Hamburg, Germany

Emergency Telephone Number: 800-662-6383

Telephone Number for Information: 800-662-6383

Date Prepared: 8/96

Signature of Preparer (Optional):

Section II – Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (Optional)
Triethyleneglykoldimethacrylate				
Bisphenol – A – glycidyldimethacrylate				
Dimethylbutlaniline				

Section III – Physical / Chemical Characteristics

Boiling Point	above 150 °C (1.05 mm Hg)		Specific Gravity (H20 = 1)	1.1
Vapor Pressure (mm Hg)	NE*		Melting Point	NE*
Vapor Density (AIR = 1)	NE*		Evaporation Rate (Butyl Acetate = 1)	<1
Solubility in Water	Negligible			

Appearance and Odor: Yellow paste, nearly odorless

Section IV – Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
above 115°C	NE*	NE*	NE*

Extinguishing Media: carbon dioxide, sand, dry chemical

Special Fire fighting Procedures: fight like fuel oil fire

Unusual Fire and Explosion Hazards: None

(Reproduce Locally): *NE – not established

OSHA 174, Sept. 1985

Section V – Reactivity Data

Stability			Conditions to Avoid
	Unstable	X	Sunlight, Heat
	Stable		

Incompatibility (Material to Avoid): Strong Acids

Hazardous Decomposition or Byproducts: Not Known

Hazardous Polymerization			Conditions to Avoid
	May Occur	X	Exposure to light, heat, contamination
	Will Not Occur		

Section VI – Health Hazard Data

Routes of Entry: Inhalation: No; Skin: Yes; Ingestion: No

Health Hazards (Acute and Chronic): Prolonged overdose can cause dyspepsia, nausea, vertigo.

Allergic reactions to methacrylates are possible.

Carcinogenicity: Not Known; NTP? ; IARC Monographs? ; OSHA Regulated?

Signs and Symptoms of Exposure: Dyspepsia, nausea, vertigo. In case of allergic reactions, typical signs and symptoms of allergies.

Medical Conditions Generally Aggravated by Exposure: Allergies to methacrylates

Emergency and First Aid Procedures: Skin contact: wash with soap and water

Eye contact: rinse with water, consult a physician

Section VII – Precautions for Safe Handling and Use

Steps to be Taken in Case Material is Released or Spilled: Absorb with inert materials such as dry sand and place in closed container for disposal as solid waste

Waste Disposal Method: Mix with inert filler and remove to open area. Allow time to cure. Use proper landfill disposal or incineration in accordance with local, state and federal regulations.

Precautions to be Taken in Handling and Storing: None

Other Precautions: None

Section VIII – Control Measures

Respiratory Protection (Specify Type): None

Ventilation				
	Local Exhaust	N/A**	Special	N/A**
No	Mechanical (General)	N/A**	Other	N/A**

Protective Gloves: N/A** Eye Protection: N/A**

Other Protective Clothing or Equipment: N/A**

Work / Hygienic Practices: Use according to directions

**N/A – Not Applicable

U.S.G.P.O: 1986-491-529/45775