

e-on® Single Dose Desensitizer

Instructions for Use

Product Description

Available in 0.075mL single-use ampoules, e-on® Single Dose Desensitizer is a desensitizing agent containing glutaraldehyde and HEMA. The glutaraldehyde and HEMA combination present in e-on® Single Dose Desensitizer acts as a flocculating constituent that strengthens collagen, and acts as an agent that creates tubular occlusion, thereby reducing post-operative sensitivity by limiting fluid movement without affecting the strength of adhesive systems.

Indications for Use - - -

e-on® Single Dose Desensitizer is indicated for reducing or preventing dentinal hypersensitivity and postoperative sensitivity in the following situations:

- Non-bonded and bonded applications
- · Temporary restorations
- Luting/cementation of indirect restorations
- · Direct restorative treatments

SINGLE-USE DEVICES

Unit dose devices are single-use devices, and are provided non-sterile. Unit dose devices must not be reused. Unit dose devices may not function as intended if re-sterilized and may result in an improper procedure and lead to improper function or failure of the device. Dispose of after use in accordance with instructions below.

Warnings and Precautions

- e-on® Single Dose Desensitizer and other glutaraldehyde-based desensitizers will burn soft tissues. Keep away from soft tissues.
- Avoid contact with eyes, skin, and mucous membranes. If accidental contact occurs, flush immediately with water. Consult physician.
- 3. Keep away from children.
- Use as directed. This product is intended for use by dental professionals only.

PROCEDURE FOR USE General Information

- For Use with Cements: e-on® Single Dose
 Desensitizer is very effective when applied to
 vital crown preparations prior to luting with
 cements, including glass ionomer and zinc
 phosphate cements.
- For Use with Amalgam: e-on® Single Dose Desensitizer can be effectively used to eliminate post-operative sensitivity under - amalgam-restorations.
- For Use with Bonding Agents: Dentin bonding agents including the 7th generation systems will benefit from the application of e-on® Single Dose Desensitizer which helps support the collagen framework for easier penetration of the adhesive without decreasing its bond strength.

Directions for Use in Non-Bonded Applications

- Clean and prepare the restoration.
- 2. Etch with 10-40% phosphoric acid for 15 to 30 seconds.
- 3. Rinse with water.
- 4. Gently dry with air (dryness is not critical).
- Apply e-on[®] Single Dose Desensitizer to the tooth using a micro brush or cotton pellet.
 Avoid contact with soft tissues.
- Wait 30 seconds, then gently dry or leave the field moist per manufacturer's instructions for the adhesive system.
- 7.1 Direct restorations: Apply bonding agent and composite material per manufacturer's

instructions.

7.2 Indirect restorations or sealing preparations: Apply adhesive and luting cement per manufacturer's instructions.

Storage

Store below $77^{\circ}F/25^{\circ}C$. Keep away from direct sunlight

DISPOSAL

Dispose of used devices which pose a risk of infection according to facility clinical waste procedures and applicable local and state regulations. To dispose of unused material, replace cap and dispose of in accordance with local and state regulations.

Definitions of Symbols

The following symbols may appear on the product packaging or labeling.

SYMBOL	TITLE	EXPLANATORY TEXT	STANDARD	REFERENCE
REF	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified	EN ISO 15223-1	5.1.6
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified	EN ISO 15223-1	5.1.5
[]i	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use	EN ISO 15223-1	5.4.3
	Use-by date	Indicates the date after which the medical device is not to be used	EN ISO 15223-1	5.1.4
1	Upper Limit of Temperature	Indicates the temperature limits to which the medical device can be safely exposed	EN ISO 15223-1	5.3.6
Rx only	Rx only	Caution: U.S. Federal law restricts this device to sale by or on the order of a dentist	US Code of Federal Regulations, Title 21	801.15(c)(1)(i) (F)
(2)	Do not re-use	Indicates a medical device that is intended for one single use only	EN ISO 15223-1	5.4.2
QTY	Quantity	Indicates the number of items within the package	N/A	N/A
MD	Medical device	Indicates the item is a medical device	EN ISO 15223-1	5.7.7
UDI	Unique Device Identifier	Indicates a carrier that contains unique device identifier information	EN ISO 15223-1	5.7.10
*	Keep away from sunlight	Indicates a medical device that needs protection from light sources	ISO 15223-1	5.3.2

