

Capsule Applicator

Carefully read the instruction before using this product.

FEATURES:

This Capsule Applicator is designed to be used with all AHL Generic encapsulated glass ionomer products to facilitate easy dispensing of the mixed materials directly to the prepared tooth.

INTENDED PURPOSE:

Capsule Applicator

INTENDED PATIENT POPULATION:

From child to geriatrics

INTENDED USER:

This product has been formulated for use in dentistry and is intended for use by dental professionals only.

CLINICAL BENEFIT:

Aid in the restoration of lost tooth structure.

INDICATIONS FOR USE:

Activation of AHL encapsulated glass ionomer products.

CONTRA-INDICATIONS:

None

CONTENTS OF PACK:

Capsule Applicator

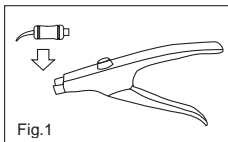
PRECAUTIONS AND WARNINGS:

- Prior to use, sterilize the capsule applicator.
- Do not use the capsule applicator on patients who have a history of allergy or show signs of allergy to metals.
- If any such reactions are experienced, discontinue the use of the product and refer to a physician.
- An operator who has a history of allergy to metals should not handle the capsule applicator.
- In case of allergy, discontinue use and consult a physician.
- Take care not to get your hand or fingers caught between the lever and the grip.
- This product should only be used by a dental professional.
- This product should only be used for the applications described herein.

PROCEDURE

(1) CAPSULE LOADING:

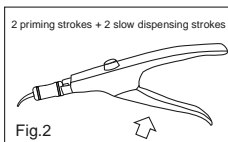
After mixing, remove the capsule from the capsule mixer: Insert and secure the capsule in capsule holder (Fig.1).



Please Note: The capsule cannot be inserted if the plunger is extended. Retract the plunger by pressing the release button.

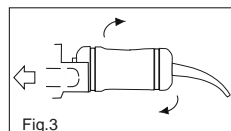
(2) EXTRUDING THE MATERIAL:

Direct the capsule nozzle into the prepared surfaced of the tooth. Make two priming strokes with the lever; then ensure the third and fourth strokes are made slowly to allow smooth dispensing of the material (Fig.2).



(3) REMOVAL OF THE CAPSULE:

Press the release button to retract the plunger. Remove the used capsule from the applicator by twisting clockwise and pulling upwards (Fig.3).



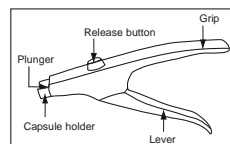
(4) CLEANING:

Clean the capsule applicator with a gauze soaked in alcohol.

(5) STERILIZATION:

The applicator can be autoclaved at 121-134°C (250-273°F) for 10 to 30 minutes (excluding heat-up time). Please follow manufacturer's instructions.

Please Note: The use of chemical disinfectants / sterilants may cause damage to the applicator and are therefore not recommended.



NAME OF PARTS:

Plunger
Capsule holder
Release button
Grip
Lever

STORAGE:



EXPIRY:



The expiry date is shown in year, month format. Do not use the product after this date.

DISPOSAL:

Dispose of the contents and containers in accordance with relevant local and national requirements.

POSSIBLE SIDE EFFECTS / RESIDUAL RISKS:

- This product contains substances that may cause and allergic reaction.

BATCH CODE:



The batch code gives an open date of manufacture in month, year, day format with a numerical suffix to uniquely identify the batch of material. Please quote this batch number in all correspondence.

DEVICE CODES:



APL1 Capsule Applicator

AHL operate a policy of continuing surveillance & monitoring of our products. If you experience any incidents relating to the use of this product, please immediately contact us at the above address stating the batch number shown on the packaging.

A summary of safety & clinical performance (SSCP) is available via the EUDAMED database.

Caution: U.S. Federal Law restricts this device to sale by or on the order of a dental professional.



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