UNODENT MD

Instructions For Use: Compule Dispenser Gun

Description of product: Unodent Compule Dispenser Gun is small, form-fitting compule dispenser gun that gives the right leverage when placing composite resins, cements, glassionomers, impression materials, needle tubes & plugs. Ergonomically designed for easy & fast loading, it accepts most carpules and is ideal for all viscosity materials.

Indication For Use: The Compule Dispenser Gun is designed to provide quick & easy dispensing of composite materials in compules that allows for direct-single patient delivery. Unodent Compule Dispenser Gun works with most standard material compules & other pre-loaded tips. Simply attach the compule to the slot of the Compule Dispenser Gun and squeeze the Compule Dispenser Gun to push & dispense dental material out of the compule easily. The smooth & effortless trigger mechanism helps maintain control of the compule tip during dispensing, and the friction-lock barrel allows for easy loading of most standard material compules.

Warning Notice: Do not autoclave beyond 275°F.

Limitation of reprocessing: Repeated processing has minimal effect on the performance, however, the end of a product's service life is therefore determined by wear and tear and damage due to going over the sterilization limit, or how the user uses & handles it.

Place of handling: Clean surface with a disposable cloth or paper towel.

Disinfection: Only use disinfecting solution suitable for synthetic material, carefully following the instructions of the respective manufacturer. Remove disinfecting solution thoroughly under running water. Do not exceed 93°C for mechanical disinfection.

Sterilization: Compule Dispenser Gun may be sterilized by all cold sterilization techniques, Ethylene Oxide (ETO), steam autoclave or chemiclave. It is autoclavable upto 275°F.

Control/Functional Check: Sight check on damages, wear, deformation.

Storage and transport: No special requirements.

The instructions have been validated as SUITABLE for preparation of a medical device and its reuse by the medical device manufacturer. It is the reprocessors' responsibility that the actual reprocessing achieves the required result with the equipment and materials applied and personnel involved in the reprocessing site. Normally. validation and routine control are necessary. Furthermore, the reprocessor should evaluate any deviation from the provided instructions regarding efficiency and possible adverse consequences.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

134°C UK CA NON STERILE TW MADE IN TAIWAN CE

REF FAX660 (116150UNODENT)

REF FAX662 (116152UNODENT)

REF FAX661 (116151UNODENT)

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Symbol	Description	Symbol	Description
REF	Product reference number	MD	Medical Device
134°C	Sterilizable in a steam sterilizer (autoclave) at temperature specified		Sterilizable in a steam sterilizer (autoclave) at temperature specified
CC	Country of Origin		Importer
UK CA	UK Conformity Assessment	EU REP	Authorized representative in the European Community
NON STERILE	No Sterile		Distributor
	Do not use if package is damaged	CE	CE marking Conformity
	Consult instructions for use	LOT	Batch or lot code
UDI	Unique Device Identifier		Use By Date

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