

Removalon[®]-I

Instrument Cleaner





EC REP MDSS GmbH Schiffgraben 41 30175 Hannover Ge

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Manufacturer: Premier® Dental Products Company 1710 Romano Drive, Plymouth Meeting, PA 19462 U.S.A. 888-670-6100 • 610-239-6000 premierdentalco.com • Made in U.S.A.



premierdentalco.com/promise

IFU# 90115-2 0421097 Rev0 PDF

INSTRUCTIONS FOR USE

Intended Use:

It is intended to dissolve carboxylate, glass ionomer and zinc phosphate cements easily, quickly and safely from instruments, ortho bands, crowns, bridges, veneers, glass slabs, inlays etc.

Device Description:

Premier[®] Removalon[®]-I is a water activated instrument cleaner removes set cements from dental instruments. Removalon[®]-I dry pack is a concentrated powder, which quickly dissolves forming a safe and effective solution.

Contraindications:

- Do not use Removalon[®]-I under the following conditions:
- If the container or cap is found broken/damaged.
- Container not able to extended fully.

PRECAUTIONS:

- Single-use only, Disposable.
- Do not mix with other detergents or contaminants.
- Keep product stored only in original container.
- Avoid over dilution.
- Extend container and recommended to fill with warm tap water.
- Wash exposed skin and hands thoroughly after handling.

WARNINGS:

- Remove contact lenses, if exposed.
- EYES Rinse with large volumes of water for 15 minutes. If irritation persists, seek medical attention.
- <u>SKIN</u> Rinse with large volumes of water.
- INGESTION Drink large volumes of water. Contact physician promptly.

Adverse Events:

- IF SWALLOWED -
 - »Harmful, may cause nausea and vomiting.
 - »May be irritating to mouth and throat.
 - »May cause allergic type reaction.
- May cause skin irritation, eye damage and allergic skin reactions.

If a serious incident has occurred in relation to the device, please report the incident to the Manufacturer and/or competent authority of the Member State where the device was used.

Contents and Setup:

ltem No.	Product/Device
9011005	Removalon-I DRY PK CASEOF 6
8101998	Removalon-I DRY PK SINGLE

Materials:

Citric Acid Anhydrous Granular formulation, environmentally friendly and biodegradable.

DIRECTIONS FOR USE:

- Pop flip-top cap or lid to open position.
- Hold bottle-up right and away from face to avoid potential dust inhalation. Pull up to height.
- Unscrew cap and fill with warm tap water to here.
- Shake well 15-20 seconds.

Without Ultrasonic Machine:

- Pour Removalon[•]-I into a metal, glass or plastic container to a depth, which will cover the areas of the instruments to be cleaned.
- Place instruments, etc. into Removalon-I and allow to soak.
- The length of time required for dissolution depends on the degree of setting and the thickness of the cements. Average time is 15 minutes.
- Prolonged immersion will cause surface discoloration. Remove after 15 minutes.

With Ultrasonic Machine:

- Fill the beaker or bath receptacle with Removalon-I.
- Immerse those instruments to be cleaned, certain that areas containing cement are covered with Removalon-I.
- Average time for cement dissolution is 5 minutes.
- After removal from Removalon-I solution rinse instruments with water.
- If Removalon-I comes in contact with skin, wash thoroughly with water.
- Removalon-I can be reused; the used solution should be discarded when a sufficient amount of debris accumulated.

Storage:

Store in a cool, dry place away from direct sunlight.

Shelf Life:

The product does not have a shelf life.

Disposal:

After use, dispose as biohazardous medical waste in accordance to facility or institutional guidelines/procedures.

For Further Information:

To obtain SDS or IFU, visit premierdentalco.com or call Premier at 610-239-6000.

Symbols	Symbol Meaning
	Manufacturer
LOT	Batch number
\wedge	Warning, See IFU
Ť	Store in dry cool place
*	Avoid direct sunlight
MD	Medical Device
UK CA	UKCA