

INSTRUCTIONS FOR USE

Pro Clean™

Professional Strength Tartar and Stain Remover for Dentures, Partials, Retainers and Night Guards





MDSS GmbH Schiffgraben 41 30175 Hannover, Ge

.CE

REP

EC



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# 90112-2 0421094 Rev0 PDF

Intended Use:

It is intended to aid in the removal of tartar and stains from Dentures, Partials, Retainers and Night Guards.

Device Description:

Premier[®] Pro Clean[™] is formulated for at-home or in-office cleaning of tartar and stains from dentures, bridges, orthodontic appliances.

Contraindications:

Do not use Pro Clean[™] under the following conditions: • Gum sensitivity or open wounds

PRECAUTIONS:

- Thoroughly rinse Dentures, Partials, Retainers and Night Guards after soaking within Pro Clean
- Single-use unit packets.
- Do not use the package if found damaged.
- Always store product in original protective packaging.
- Avoid over dilution.
- Wash exposed skin and hands thoroughly after handling.
- Contains Sulfamic acid, which may cause eye and skin irritation.

WARNINGS:

- Irritation may occur if not fully rinsed off.
- Remove contact lenses, if exposed.
- <u>EYES</u> 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:

- May be harmful if swallowed.
- May be harmful if inhaled.
- Moderate eye and skin irritant.

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
9011102	Pro Clean STAIN CLEANER (CASE OF 10)
9011103	Pro Clean STAIN CLEANER (SINGLE BOX)
9011992	Pro Clean SAMPLE (1pk)

Materials:

Sulfamic Acid Crystalline formula and has fresh mint scent.

DIRECTIONS FOR USE:

In -Office:

- Add contents of packet into a breaker or resalable plastic bag containing 16oz. of very warm (100-125°F/38-52°C) water.
- Immerse beaker or sealed plastic bag in ultrasonic bath for 1-5 minutes, depending on the severity of the stain.
- Rinse thoroughly with tap water after cleaning to remove residual cleaner from appliance.

At-Home:

- Add contents of packet into a container with 16oz. of very warm (100-125°F/38-52°C) water.
- Allow appliance to soak for at least two (2) hours.
- ${\boldsymbol \cdot}$ Rinse thoroughly with tap water after cleaning to remove residual cleaner from appliance.

Use one packet per cleaning.

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