



Description:

Kool White is a professionally-dispensed toothwhitening system specially formulated to remove tooth discoloration due to foods, tobacco, and other stain-causing materials. Its patented technology has been clinically proven to whiten teeth safely and effectively in two weeks.

Kool White carbamide peroxide gel is available in 10%, 15%, or 20% carbamide peroxide concentrations. This complete tooth whitening system has unique qualities including prolonged activation time, adhesive properties, and custom-designed application tooth tray.

Instructions for Dentists:

Kool White is to be used for cosmetic whitening of teeth for patients with normal oral health status. When recommending treatment, first evaluate the oral health status of the patient and discuss level of whitening desired. Inform the patient that the amount of whitening that can be achieved will depend on the type of staining. Advise patients that composite fillings and ceramic restorations will not be whitened or altered in shade.

Kool White tooth whitening system should be used prior to placement of composites, veneers and/or crowns, and bridges. This will allow for the proper matching to the new lighter shades of the teeth obtained by cosmetic whitening. We recommend waiting at least 2 weeks following the whitening treatment to ensure shade stabilization and maximum bond strength.

Important:

Please read this notice before using any tooth whitening products. WE, AT PAC-DENT INTERNATIONAL, INC., URGE ALL CUSTOMERS TO PLEASE CONSULT A DENTIST FOR A THOROUGH DENTAL EXAMINATION BEFORE USING ANY AT HOME TOOTH WHITENING SYSTEM.

Dental Work:

Tooth Whitening (bleaching) gel will only whiten natural teeth. It will NOT bleach (whiten), nor harm bonding, caps, crowns, bridges, fillings or any other artificial dental work. You may have to have the dentistry redone in order to match your new white teeth.

Tetracycline (an antibiotic) stained teeth or grayish teeth are more difficult to bleach and have a varied prognosis. Exposed root portion of teeth which occurs



For Best Results:

- Leaky restorations and/or areas of caries should be treated before whitening treatment. If a
 tooth-colored restoration is indicated, a temporary restoration should be placed prior to
 whitening and the final restoration placed after whitening. Exposed root surfaces may
 experience sensitivity during toothwhitening treatment. If large areas of root are exposed or
 if restorations are inadequate, patients can develop mild to moderate sensitivity.
- Exposed root areas can be handled by simply trimming back the tray to avoid irritation.
 Alternatively one can cover the area with an adequate dentin bonding agent and layer of Bis GMA or similar resin. Cleaning, drying, and placing a layer of a dentin sealant may provide quick and temporary relief from irritation.
- Perform a prophylaxis to remove calculus and external stains prior to whitening procedure.
- Check tray for fit and comfort.
- Demonstrate the whitening treatment procedure to the patient by following the Patient Instructions provided in the kit. Kool White tooth whitening system is recommended for daily use of one or two treatments of 30 minutes to one hour each for two weeks.
- Soft tissue health is critical to minimize tissue trauma. Patients should be informed of
 potential tooth sensitivity before treatment. If the patient experiences discomfort and/or
 sore, reddened areas persist and/or teeth ache for any length of time, instruct patient to
 remove the tray and consult your office for adjustments to tray and/or treatment schedule
 adjustments.
- Advise patients to discontinue use of appliance if discomfort occurs. If teeth become overly
 sensitive to cold before treatment is complete or if sensitivity persists or worsens, have the
 patient contact your office for instructions. If you feel necessary, 1-3 days rest from treatment
 may be required.
- Record patient's initial teeth shade by using shade guide (as shown in picture). Monitor patient's treatment progress.

Tray Storage:

When the tray is not in use, it should always be stored in the provided tray case. The tray should be cleaned and rinsed prior to placing in the appliance case each time. Teeth should be cleaned (brushing is adequate) prior to tray insertion.



with gum recession will also not bleach. If the patient has amalgam (silver) fillings in, near or behind the front teeth, long term bleaching can cause the surrounding tooth to have a greenish tinge. Bleaching teeth which have a lot of translucency (see-through) can cause the teeth to become even more translucent and may give the tooth a darker appearance.

Sensitivity:

The patient's teeth or gums will most likely become sensitive. This is common while using all products containing peroxide based gels and it is not harmful. In case of increased sensitivity reduce usage time and/or frequency until the sensitivity subsides. Due to the high prevalence of sensitivity, it is recommended to use desensitizing gel following bleaching routinely.

Warning:

Keep bleaching gel out of reach of children. Do NOT use if pregnant or during nursing. Do NOT smoke, drink or eat while bleaching your teeth. DENTAL WHITENING GEL SHOULD BE REFRIDGERATED FOR LONG TERM STORAGE. Shelf life is 1 year un-refrigerated and 2 years refrigerated. Use only in accordance with these instructions.

Whitening Tray Fabrication:

- 1 Take an alginate impression of the arch to be whitened. Pour model from alginate impression with plaster or dental stone. This should be carried out as soon as possible after the impression is taken to maximize accuracy.
- 2 Resin Spacer LC is used to create reservoir spaces in tooth trays. Carefully apply 0.5mm of Resin Spacer LC material onto the desired labial surfaces of the impression model. Stay 1.5mm away from the patient's gingival line. Lapping onto gingiva may irritate tissues, and cause sensitivity problems.
- 3 A 2-minute curing session should be applied to the Resin Spacer LC (using any LED curing light). Alternatively, a hand-held intraoral curing light can also be used, cure 20~40 seconds per tooth. Wipe off oxygen inhibition layer afterwards.
- 4 Use a vacu-form to heat the soft-tray until it sags approximately 1-2 inches. Lower the clamp holder with tray material over the stone or plaster model. Turn switch to "vacuum" and allow the softened plastic to adapt over the model.
- 5 When the tray has completely cooled, trim excess using small curved surgical scissors. Trim 1 mm away from the gingiva and scallop around the interdental papillae. A non-scalloped tray can also be used. Check the tray for fit on the model.

Precautions:

- Monitor and fit tray. Design and plan or adjust treatment regimen to maintain patient comfort.
- Restorations should be free from defects and all exposed sensitive dentin covered. Areas
 may be exposed due to occlusal wear, gingival recession, and abrasion. If areas are
 sensitive, treat with proper restoration or dentin bonding agent. This area may also be
 treated temporarily with a dental sealant.
- Inform patient to remove tray and discontinue treatment if soreness of gums and/or teeth persists and to contact your office for instructions.
- Instruct patients not to over-fill tray with whitening paste.
- Kool White should not be used on children aged 13 and under.
- Kool White is not to be used during pregnancy or while nursing.
- Store at or below 24°C (75°F). Do not freeze.
- To help maintain the whitening benefit of Kool White tooth whitening system, have your patients brush their teeth daily with fluoride toothpaste, which can be found in most stores.

Comprehensive clinical and laboratory studies have shown Kool White tooth whitening system to be safe and effective when used as directed.

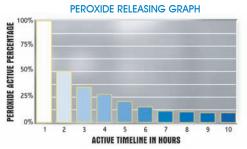
Instruction for Patients:

It is important that you apply the Kool White teeth whitening gel properly so you do not waste any of the gel and that you experience the least amount of sensitivity while using the gel.

- 1 Prior to Treatment: Brush and floss just prior to bleaching your teeth. The whitening gel is the most effective with clean teeth. Try the custom-fabricated trays (obtained from your dentist) in first without any beach to check the fit and comfort.
- 2 Applying the Bleaching Gel: Make sure that the bleaching trays are clean and dry before applying the whitening gel. Moisture reduces the efficiency of the whitening gel and slows down the whitening process. When you apply the gel, make sure not to fill the trays. Place a SMALL drop of tooth whitening gel half way up on the inner front surface of tray (in the front of each tooth in the tray). Do not spread the bleach around. Recap the syringe for next treatment until empty. The average treatment per arch requires approximately 0.5ml of whitening gel.

- 3 Inserting the Bleaching Trays: Insert whitening tray in the mouth over the teeth. Seat the tray firmly against the teeth. Wipe the excess gel, which seeps over the brim of the tray onto your gums, by holding the tray up with one hand, wipe the excess gel off of the gums with your finger or tissue. Wear the tray with the gel as directed by your dentist or as below.
- 4 Wearing Time: We recommend that if you have not whitened before, use for 30 min to 1 hour the first time and increase the wearing time if there is little or no tooth sensitivity.

Studies have shown that Kool tooth whitening gel posesses sustained active status for up to 9 hours when worn by patients while they sleep. But more attention must be given to the fabrication of trays in orde to limit peroxide contact to tooth surfaces, rather than spilling onto soft gum tissues.



- 5 When treatment has been completed, remove mouth tray. Brush your teeth with a wet toothbrush to remove any adhered whitening paste. Rinse mouth tray under water, using a wet toothbrush to clean excess whitening paste from tray. Between treatments, store mouth tray in the storage case provided.
- 6 Repeat steps 1 through 5 for each treatment prescribed by your dentist. If you experience discomfort from sensitivity, ask your dentist about a treatment to help reduce sensitivity. As always, consult with your dentist if you have questions.

Longer wear times create faster whitening results. Faster results can be achieved with higher concentrations of Carbamide Peroxide or hydrogen peroxide. 50% of the bleaching takes place in the first 1-2 hours. Conduct your whitening session once per day until desired level of whitening is attained.

Ingredients:

Distilled Water, Carbamide Peroxide, Glycerin, Flavor, Buffered Polyacrylic Acid.

- 9 1.2 ml unit dose syringes with dispensing tips
- 1 Resin Spacer LC (1.2ml)
- 2 Tray sheets
- 1 Pocket Tray case

Product Shelf Life:

24 months under refrigeration, 12 months in cool dry places. Please refrigerate to maintain shelf life and product effectiveness.

Keep out of reach of children.

Dentist dispensed.

Destroy after use.

Syringe not for injection.

Irritant to skin and eye.







Manufacturer:



Pac-Dent International, Inc.

21078 Commerce Pointe Dr. Walnut, CA 91789, USA www.pac-dent.com

PAC-DENT

ΜΑΤΕΡΙΔΙ ΚΑΓΕΤΥ ΠΑΤΑ SHEET

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/PREPARATION	
Material Name Kool White	Manufactured by Pac-Dent International, Inc.
Material Use Tooth Whitening Gel	21078 Commerce Pointe Dr.
	Walnut, California 91789 U.S.A.
	Emergency Contact 1-909-839-0888
SECTION 2 - COMPOSITION/INFORMATION ON INGREDIENTS	
Active Ingredients	CAS or UN Numbers
Carbamide Peroxide	124-43-6
SECTION 3 - HAZARDS IDENTIFICATION	
Adverse Human Effects and Symptoms Not defined.	
SECTION 4 - FIRST AID MEASURES	
Inhalation Not defined	Eye Contact Flush with generous amount of water
Skin Contact Wash with soap and water	Ingestion Drink large amounts of milk or water
SECTION 5 - FIRE-FIGHTING MEASURES	SECTION 6 - ACCIDENTAL RELEASE MEASURES
Flamability None	Personal & Environmental Precautions None
Means of Extinction N/A	Methods for Cleaning Any conventional cleaning methods.
SECTION 7 - HANDLING AND STORAGE	SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION
Handling Precautions Not defined.	Respiratory Protection None. Eye Protection Safety goggle
Storage Requirements Refrigerate when not in use.	Hand Protection Latex gloves Skin Protection Lab coat
SECTION 9 - PHYSICAL & CHEMICAL PROPERTIES	
Appearance Clear viscous gel.	Solubility in H ₂ O Completely Melting Point Not defined.
Odor Flavored pH 6~7	Other Data None
SECTION 10 - STABILITY AND REACTIVITY	
Chemical Stability Not stable. Conditions & Materials to Avoid Heat &	z sunlight, oxidizable materials. Hazardous Decomposition Products N/A
SECTION 11 - TOXICOLOGICAL INFORMATION	
Route of Entry Skin contact, eye contact, ingestion.	Sensitization Not defined.
Effects and Symptoms of Short-Term Exposure Skin: slight irritation;	eyes: irritation; ingestion: irritation unlikely in small amounts
Chronic Effects and Symptoms of Long-Term Exposure Skin: slight irrita	ation; eyes: irritation; ingestion: irritation unlikely in small amounts
SECTION 12 - ECOLOGICAL INFORMATION	SECTION 13 - DISPOSABLE CONSIDERATIONS
Biodegradability Not defined	Method of Waste Disposal In accordance with government regulatio
SECTION 14 - TRANSPORT INFORMATION	SECTION 15 - REGULATORY INFORMATION

FOR DENTAL USE ONLY. Use as directed.

None

Further Details

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process. Such information is to the best of the company's knowledge and believed accurate and reliable as of the date indicated. However, no representation, warranty or guarantee of any kind, express or implied, is made as to its accuracy reliability or completeness and we assume no responsibility for any loss, damage or expense, direct or consequentla, arising out of use. It is the user's responsibility to satisfy himself as to the suitableness and completeness of such information for his own particular use.



Special Note from your Dentist:

Your next Dentist Visit is on:____/_

You have completed



26 (28

whitening sessions.