

DENTSPLY
DeTREY

Illuminé™

Professional Bleaching



With the compliments of

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TECHNICAL MANUAL



Table of contents

1	Introduction.....	1
2	Tooth Discoloration.....	2
2.1	Extrinsic Stain	3
2.2	Intrinsic Stain	4
2.3	Tooth Discoloration Due to Structural Abnormalities	5
2.4	Tooth Discoloration Due to Ageing	6
3	Techniques for Tooth Whitening	7
3.1	Vital Tooth Bleaching	7
3.1.1	At-Home Whitening.....	7
3.1.2	In-Office Whitening.....	8
3.2	Non-Vital Tooth Bleaching	9
3.2.1	Walking Bleach Technique.....	9
3.2.2	Thermocatalytic Technique.....	9
4	Chemistry of Whitening.....	10
5	An Open Legal Situation in the European Community?	14
6	Illuminé™ Tooth Whitening System.....	16
6.1	Indications and Contraindications	16
6.2	Interactions with Dental Materials	17
6.3	Tray Manufacturing	18
7	Illuminé home	21
7.1	Product Description.....	21

7.2	Composition and Working Mechanism	21
7.3	Clinical Investigations	22
7.3.1	Clinical investigation of Illuminé home 10% by Swift et al at UNC (1997) ..	22
7.3.2	Clinical investigation of Illuminé home 10% by Barnes et al at the University of Maryland (1998)	24
7.3.3	Clinical investigation of Illuminé home 10% and 15% by Kihn et al at the University of Maryland (2000)	26
7.4	Step-by-Step Instructions.....	28
8	Illuminé office	30
8.1	Product Description.....	30
8.2	Composition and Working Mechanism	31
8.3	In-Vitro Data Evaluation of the Enamel Surface Morphology in Teeth Treated with Illuminé office by Sherman J, DENTSPLY Professional.....	32
8.3.1	Summary	32
8.3.2	Methods.....	32
8.3.3	Results.....	33
8.3.4	Conclusion	36
8.4	Clinical Investigations	36
8.4.1	A Clinical Study Evaluating the Efficacy of a New Chairside and Take-Home Bleaching System – Final Report, January 27, 2000 by Bardwell D, Papathanasiou A, Tufts University Dental Clinic.....	37
8.4.2	Clinical Evaluation of a 15% In-Office Hydrogen Peroxide Tooth Whitening Touch Up Agent - Updated Report April 24, 2000 by Kihn P W, Barnes D M, Adachi E, The University of Maryland Dental School	38
8.4.3	In-House Whitening Case Study FP 084 – Report February 4, 2000 by Sherman J, DENTSPLY Preventive Care.....	40
8.5	Step-by-Step Instructions.....	40

9	References and Selected Literature	44
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1 Introduction

A range of developmental abnormalities, acquired diseases, and degenerative changes result in tooth discolourations which cannot be removed by simple brushing or professional tooth cleaning and use of abrasives. For the treatment of such stains, chemical bleaching is a conservative, tooth substance saving alternative to other restorative procedures such as veneering or the placement of crowns.

For treatment of the above-mentioned diseases but also for pure cosmetic indications, the DeTrey Division of DENTSPLY offers under the brand *Illuminé* a system of professional tooth whitening products.

Illuminé home 10% and 15% are carbamide peroxide-based whitening gels for dentist-monitored at-home treatment. The 15% fluoride-containing version offers a faster and more intensive whitening effect than the conventional 10% version.

Illuminé office makes use of a new, innovative chemical concept and delivery form for the controlled release of hydrogen peroxide. It lightens up to 9 shades in 30 minutes without heat, light, or gingival isolation. *Illuminé office* is recommended as a pre-treatment boost to *Illuminé home* Tooth Whitening Gels or as a stand-alone treatment.

The *Illuminé* Tooth Whitening products, their presentations forms, and the product information (separate booklets for dentist, patient, and dental technician) have been specifically developed to meet the requirements set by the European Commission for Medical Devices.

2 Tooth Discoloration

In the field of conservative aesthetic dentistry, tooth bleaching meets the demand of *non-destructive* treatment of discoloured teeth in a variety of indications. However, success and efficiency of the bleaching treatment, and the selection of the most suitable technique and clinical procedure depend upon several issues to be considered. One characteristic all tooth bleaching procedures have in common is the oxidative elimination or at least the decrease in dental stains (please see Chapter 4 for details on the chemistry of this process). It is obvious that bleaching success depends on the nature of the dental stain. To avoid masking of pathological conditions, it is mandatory that the reason for the discoloration is understood prior to treatment.

The clinically perceived shades of unstained teeth are determined by the inherent dentine and enamel shades as illustrated in Figure 1. The overall shades of discoloured teeth are a combination of tooth stain and the inherent tooth shade (Spouge 1973; Viscio et al. 2000).

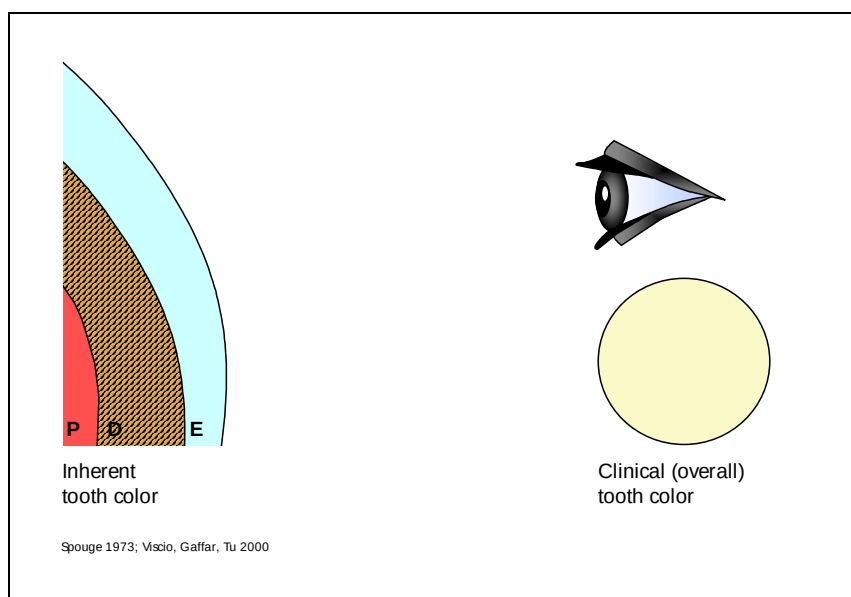


Figure 1 The clinically perceived shade of unstained teeth is determined by the inherent dentine and enamel shades (Spouge 1973; Viscio et al. 2000). P: pulp; D: dentine; E: enamel.

Commonly, tooth discoloration is classified regarding location and aetiology of the stain. In general, dental discoloration can be grouped into extrinsic and intrinsic stain depending on

the location of chromophors causing stain. Extrinsic stain is confined to the tooth surface whereas intrinsic stain, i.e. discoloration of the dental hard tissue, is caused by colouring compounds deposited or permeated into dentine and/or enamel. On ageing, translucent enamel gets thinner; the apparent tooth colour is then determined by the darker dentine shades. Structural abnormalities of enamel or dentine count among other reasons for tooth discoloration.

2.1 Extrinsic Stain

Extrinsic stains are caused by the deposition of chromogenic material on the tooth surface wherein adhesion of the chromogens on the tooth surface plays a critical role. The tenacity of chromogen adhesion is determined by the interaction forces, but these mechanisms are not yet fully understood. However, in the case of typical tannin chromogens causing e. g. tea, coffee and red wine stains, adhesion of chromogens via saliva proteins on the tooth surface is assumed as outlined in Figure 2 (Nathoo, 1997). Saliva proteins are selectively bonded via calcium bridges, thus forming the pellicle. At the early stage of staining, chromogens themselves are assumed to interact with the pellicle via hydrogen bridges. At this stage, food stains can be removed by tooth brushing with standard tooth pastes. However, food and tobacco stains are known to darken and become more tenacious over a longer period of time. Especially the cervical portions of the teeth adjacent to the gingival margins often become yellowish or brownish. Chemical analysis of aged stains of food and beverages revealed the presence of furfurals and furfuraldehyde derivatives. These compounds are products of the Millard reaction (nonenzymatic browning reaction), which is a series of chemical rearrangements and reactions between sugars and amino acids (Viscio et al. 2000). Ageing of extrinsic stains is not yet fully understood but seems to be related with the strengthening of the bonding of chromophors to the tooth surface. Usually, these aged extrinsic stains cannot be removed by tooth brushing. Professional cleaning with abrasive pastes or whitening with a bleaching agent are necessary to lighten teeth. Tenacious surface stains are highly amenable to bleaching, although stains are more difficult to remove from pits, fissures, grooves, or enamel defects (Goldstein et al. 1995).

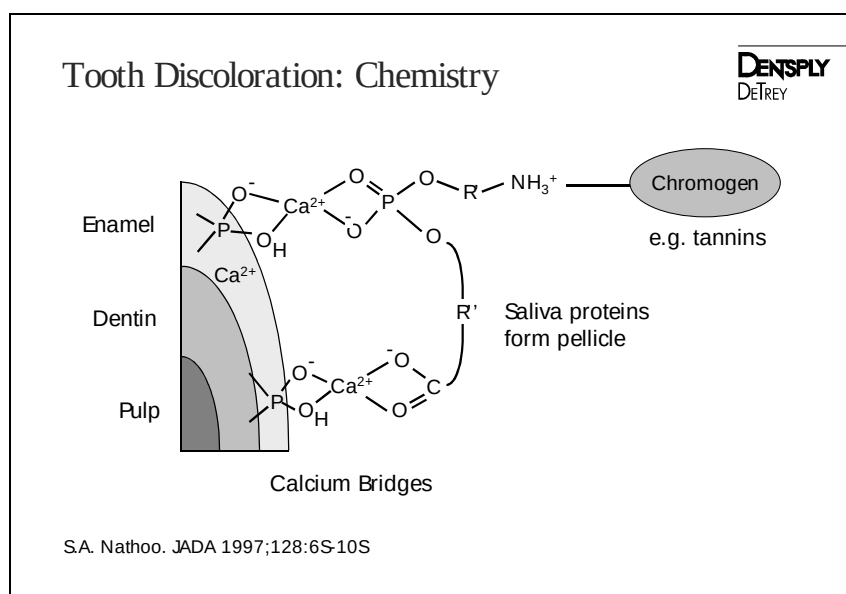


Figure 2 Model of the interaction of tannins with the pellicle (Nathoo 1997).

Binding of colourless materials to teeth with subsequent reaction to chromogens may also result in extrinsic stains. For example, colourless stannous fluoride is prone to reduction to tin by sulfuryl groups of pellicle proteins causing dark external metallic stain. Another example is brown stain caused by redox reactions of chlorhexidine. Removing stains of antimicrobial agents requires bleaching with oxygenating agents (Nathoo 1997).

2.2 Intrinsic Stain

Unlike extrinsic discoloration, intrinsic discoloration is due to chromogenic material located within the dentine or enamel. Aetiology of intrinsic discoloration can be pre-eruptive and/or post-eruptive. Intrinsic stains are not removable by brushing or any abrasive process, but can be reduced by bleaching with agents penetrating enamel and dentine to decolourise the chromogens. However, persistent intrinsic stains may be treated for a longer period than extrinsic discoloration to lighten teeth and sometimes bleaching does not eliminate discoloration totally.

The devastating effect of some medicamentation given systematically, especially during tooth formation, is displayed by teeth of young people with yellow, brown or grey intrinsic stains of the antibiotic tetracycline. The severity of stains and specific colour depends on the duration of administration of tetracycline and the stage of tooth formation at the time of use. Teeth are most susceptible to tetracycline discoloration in early childhood during tooth

development and even pre-natally, beginning with the second trimester of pregnancy. It is believed that tetracycline is incorporated into the tooth structure during calcification via complexation with calcium ions. The dye causing the discoloration results from a photochemical reaction of these complexes when tetracycline affected teeth are exposed to sunlight, which is why the labial surfaces of the incisors tend to darken more quickly to grey or brown while the molars remain yellow for a longer time (Goldstein et al. 1995). Fully formed teeth in adults may be stained from taking the tetracycline Minocycline for acne. This discoloration can be caused from deposition of tetracycline in secondary dentine as well as from soaking in saliva (Haywood 2000).

Serious tetracycline stains are rather persistent and using bleaching, discoloration can often only be reduced (Glockner et al. 1997; Haywood 1997). However, on extending treatment time and concentration of active ingredient, lightening of even dark tetracycline stains can be achieved (Leonard 2000, Haywood 2000).

Teeth can acquire intrinsic stains after eruption due to trauma on the teeth. Blood penetrates into the dentine tubuli and the degradation products and iron complexes cause discoloration. For the same reason, in some cases endodontically treated non-vital teeth exhibit discoloration after some time. These discolorations can be reduced or even removed by bleaching. However, with non-vital teeth, preference is usually given to internal bleaching, since in this case it is more efficient than an external bleaching procedure (see Chapter 3). Intrinsic stains caused by blood degradation products deposited within the dentine can also be caused by haematological disorders such as erythroblastosis fetalis, thalassemia, and sickle-cell anaemia because of the affected coagulation system (Nathoo 1997; Viscio et al. 2000).

Another source of intrinsic stains are aged dental materials like root filling materials, zinc oxide eugenol cements, or amalgam (Glockner et al. 1997).

2.3 Tooth Discoloration Due to Structural Abnormalities

Fluorosis is a typical disease resulting in abnormal structure of the enamel. Endemic enamel fluorosis is caused by excessive intake of fluoride during enamel formation and calcification, resulting in discoloration and surface defects, so called “mottled enamel”. Typically, affected teeth show paper-white flecks, areas of yellow to brown or even dark grey stains. If mottling is serious enough, enamel appears opaque, chalky without glaze and lustre of healthy teeth. Bleaching is viewed to be useful to lower contrast between these white areas and the dark stains to improve aesthetics. Bleaching can also be an adjunctive treatment preceding

veneering. However, if fluorosis caused severe lack of enamel or bare dentine, bleaching should not be used at all (Goldstein et al. 1995).

2.4 Tooth Discoloration Due to Ageing

Changes in tooth colour almost inevitably accompany ageing. Most newly formed teeth exhibit rather thick, even enamel which modifies the inherent base colour of the underlying dentine resulting in an milky white appearance – the aesthetic ideal in today's society. Numerous genetic, environmental, medical, and dental causes described above move away from this ideal due to dental stains. As foods, beverages, and nicotine have cumulative staining effect, teeth usually darken on ageing. Additionally, stains become more tenacious and darker due to chemical reactions. Microcracks and defects in the enamel surface enable extrinsic chromophors to penetrate into the enamel that results in intrinsic stain. On ageing, thinning of enamel also causes a shift to a darker apparent colour. At the same time as the enamel becomes thinner secondary dentine is deposited which is a natural protective mechanism. The combination of all factors creates an old looking tooth. Usually, unless the enamel is badly worn, bleaching is an efficient technique to lighten teeth of older patients (Goldstein et al. 1995).

3 Techniques for Tooth Whitening

Techniques for tooth whitening can be classified and described according to:

a) The vitality status of the teeth to be treated:

Vital bleaching vs. **non-vital bleaching**

b) Where and by whom the bleaching substance is applied:

In-office bleaching vs. **at-home bleaching**

3.1 Vital Tooth Bleaching

Vital teeth are bleached by application of the whitening substance on the external surface of the teeth. The whitening procedure can be carried out in the dental surgery or at home by the patient or by a combination of both techniques.

3.1.1 At-Home Whitening

[Synonyms: Nightguard vital bleaching]

At-home whitening involves the use of a 10 – 15% carbamide peroxide material applied in a custom-made tray for a certain number of hours per day or during sleep. Treatment is carried out by the patient himself, but the process is monitored by the dentist during recall appointments.

Advantages:

- Bleaching is carried out with less aggressive chemicals.
- The prolonged treatment time makes it easy to determine when the desired result is obtained.
- Due to reduced chairtime, less costly for the patient.

Disadvantages:

- Relatively long treatment time.
- Not recommended in patients with limited compliance.

CRA data (Christensen, 1997) show that most products have lost 80% of their active ingredient within 2 hours after placement in the mouth. All-night bleaching is therefore questionable from the point of view of effectiveness. However, some patients prefer this schedule as it does not interfere with their normal activities.

In most cases, the treatment period is between 1 and 6 weeks.

According to Haywood, 1997, the technique was first published in 1989 and can be traced back to 1968.

Guidelines by the American Dental Association, latest revision May 1998, recommend suitable in vitro and clinical tests to investigate safety and efficacy.

3.1.2 In-Office Whitening

[Synonym: In-office bleaching]

With in-office bleaching, the whitening procedure is carried out in the dental surgery by the dentist or under his supervision. The procedure usually takes 30 to 60 minutes. Several appointments may be necessary to achieve the desired result.

At present, hydrogen peroxide is considered to be the most effective vital bleaching agent for in-office application. According to Haywood, 1998, this technique was already applied by Harlan back in 1884.

Bleaching agents vary from a solution of 35% hydrogen peroxide to various gels of greater or lesser content. The process can be applied to an entire arch or to a single tooth only. Nowadays, it is believed that an external energy source (heat, light, laser) does not enhance the whitening reaction.

Advantages:

- Instant result: Patient leaves surgery with whiter teeth.
- The complete process is under the control of the dentist.
- Process is independent from patient compliance.

Disadvantages:

- Gingival isolation by rubberdam or a rubberdam substitute is necessary.
- Complex application technique and use of potentially harmful, highly aggressive chemicals.
- Higher costs incurred for the patient due to extended chairtime.
- Several appointments may be necessary to achieve the desired result.

With Illuminé office (see Chapter 8.1), most disadvantages of conventional in-office systems are overcome.

3.2 Non-Vital Tooth Bleaching

[Synonyms: Internal bleaching]

Non-vital tooth bleaching refers to the whitening of tooth discolorations caused by traumatic damages of the pulp, pulp necrosis, or endodontic treatment.

Non-vital teeth are bleached by application of the whitening substance into the prepared pulp chamber and coronal part of the root canal. In addition to this internal bleaching, a suitable whitening substance may also be applied onto the external surfaces of the tooth.

30% hydrogen peroxide solution alone or mixed with sodium perborate, or sodium perborate mixed with water are common formulations for non-vital tooth bleaching. The whitening agent is supplied into the pulp chamber in 2 different techniques:

3.2.1 Walking Bleach Technique

The bleaching agent (sodium perborate mixture) is sealed in the pulp chamber to allow slow activation over several days.

3.2.2 Thermocatalytic Technique

The complete treatment is carried out in the surgery and involves the repeated application of a 30% hydrogen peroxide solution which is activated by heat over a period of about 30 minutes.

4 Chemistry of Whitening

Bleaching is a chemical process which is widely applied for whitening materials mostly using oxidising compounds, e.g. hydrogen peroxide, chlorine or sodium hypochlorit. Although bleaching processes are complex sequences of chemical reactions, the underlying principle of the vast majority is the stepwise oxidation of dyes to decolourise them. Total oxidation of organic chromogens via several intermediates ends up in the final products carbon dioxide CO_2 and water H_2O . The extent and the rate of oxidation can be controlled by the bleaching conditions (e.g. oxygenating agent, concentration, duration of bleaching, and temperature). Control of chemical bleaching is important for its feasibility in dentistry with respect to dental health and safety.

In dentistry, modern bleaching materials contain oxidising peroxide compounds, i. e. hydrogen peroxide H_2O_2 or carbamide peroxide (CP). Carbamide peroxide is a 1:1 complex of urea and hydrogen peroxide. Hydrogen peroxide is stabilised in this complex. In the presence of compounds prone to oxidation, hydrogen peroxide is released (Figure 3). The released hydrogen peroxide, but not urea has an oxidising capacity. 1.00 g carbamide peroxide is equivalent to 0.36 g hydrogen peroxide when completely released.

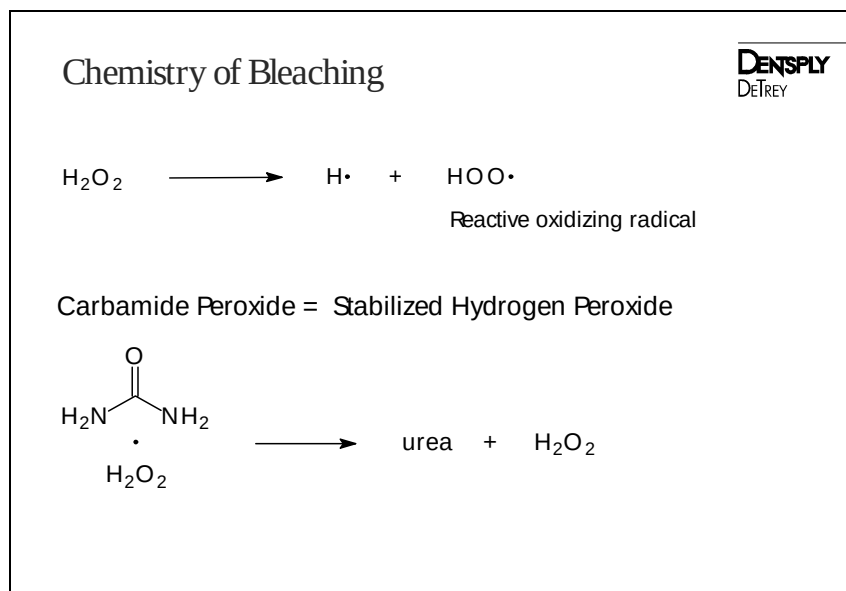


Figure 3 Carbamide peroxide (CP) is a 1:1 complex of urea and hydrogen peroxide. Hydrogen peroxide is stabilised in this complex. In the presence of compounds prone to oxidation, hydrogen peroxide is released.

The mechanism of vital tooth whitening with peroxide containing bleaching gels is illustrated schematically in Figure 4. The bleaching gel is administered on the surface of discoloured teeth. Peroxide is released from the gel and can permeate into the enamel and dentine. Therefore, not only extrinsic staining dyes but also intrinsic chromogens can be oxidised to colourless products.

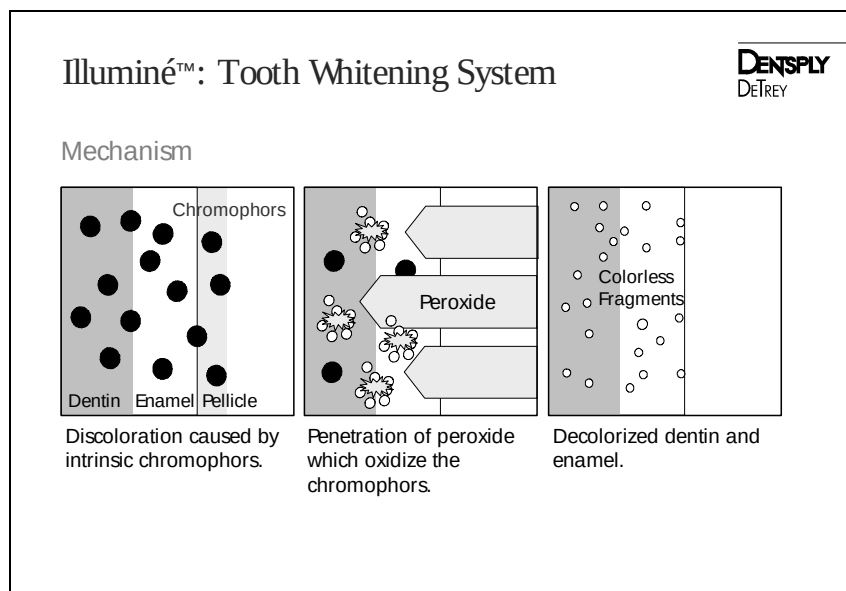
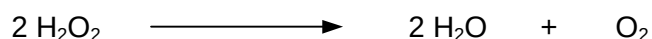


Figure 4 Schematic illustration of the mechanism of bleaching with peroxides. Peroxide is released from the bleaching gel administered on the tooth surface and diffused into tooth hard tissues. Peroxide attacks extrinsic and intrinsic staining chromogens which results in decolourising dyes via an oxidation mechanism.

The oxidation process of organic compounds with hydrogen peroxide is a complex series of reactions. Hydrogen peroxide is a metastable liquid with a rather high tendency to decomposition into water and oxygen according to



The decay of hydrogen peroxide is enhanced with increasing temperature and by irradiation with UV light, and also depends on the pH value. To reduce breakdown and to extend shelf life, hydrogen peroxide is usually available in acidic aqueous solutions and has to be stored dark and refrigerated. A 30% aqueous solution of pure hydrogen peroxide has roughly pH 3. An elevated pH accelerates decomposition. In the presence of catalysts, like several metal ions and metal oxides, and natural enzymes, e.g. peroxidase and catalase, decomposition is strongly enhanced. The hydrogen peroxide breakdown is a radical process. The first step of the radical mechanism is the formation of the hydroxyl radicals $\text{HO}\cdot$ inducing a chain reaction. In the course of the reaction dioxygenyl radicals $\text{HOO}\cdot$ are also formed. Hydroxyl and dioxygenyl radicals are highly reactive and attack organic material to oxidise it. Especially compounds with unsaturated double bonds are highly prone to oxidation with these radicals. Typically, staining organic chromogens are characterised by conjugated double bonds in the molecule, which is the structural reason for the colour. Via several

intermediate steps, the oxidation reaction of the dye molecules results in colourless hydrophilic molecules comprising hydroxyl groups (HO-groups). This is illustrated schematically in Figure 5.

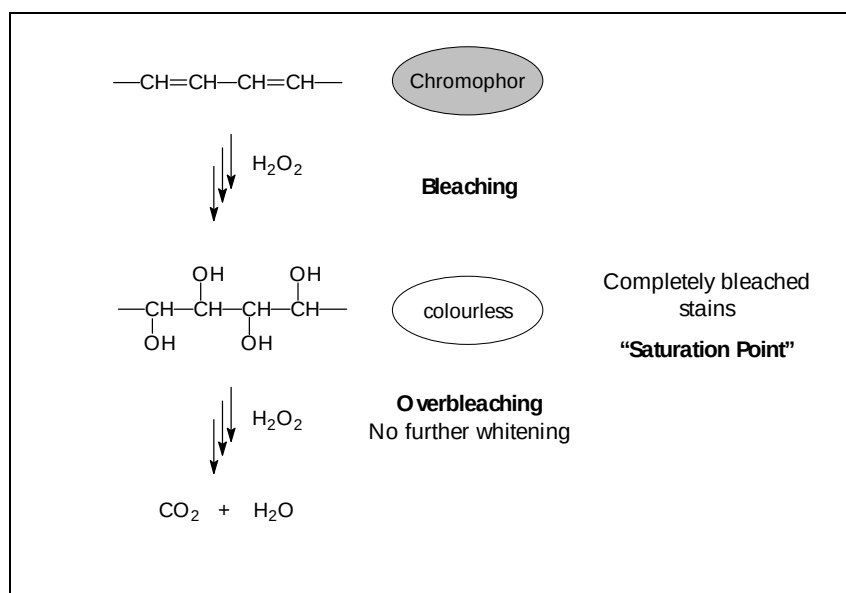


Figure 5 Schematic illustration of the chemical oxidation reaction of dye molecules comprising unsaturated double bonds with hydrogen peroxide to colourless molecules. After conversion of all stains to colourless product the saturation point is reached. Further bleaching would only cause degradation to carbon dioxide and water but would not increase the whitening effect (overbleaching).

As bleaching proceeds, teeth continually lighten. When all chromophors are converted to colourless molecules, the so-called saturation point is reached. Further bleaching, i.e. overbleaching, would cause further oxidation resulting in degradation to carbon dioxide and water, but would not increase the whitening effect. Neither does it improve the brightness of the teeth. At the saturation point, further lightening of teeth slows down dramatically. Excessive overbleaching bears the risk to oxidise proteins of the enamel and dentine which may cause significant alteration of the enamel and dentine structure. Reduction of the tooth structure by loss of enamel may be the consequence (Goldstein et al. 1995). Therefore, it is demanded that in-office bleaching be carried out by a dentist and that home-bleaching be supervised and regularly controlled by a dentist. Overbleaching with over-the-counter nightguard products and without supervision by a dentist is of particular concern (Haymann et al. 1997).

5 An Open Legal Situation in the European Community?

When tooth whitening products started to appear in Europe at the beginning of the nineties, a dispute has arisen whether these products are legally defined as cosmetics or as medical devices.

Tooth Whiteners as Cosmetic Products

On 15th February 1996, Mrs. Bonino announced in the name of the Commission of the European Community that all tooth whitening products are cosmetic products as defined by the Council Directive 76/768/EEC. The active substance of tooth whitening products, hydrogen peroxide, is regulated by the Directive 92/86/EEC. The 15th adaptation of this Directive of 1st July 1993, allows a maximum concentration of 0.1% hydrogen peroxide. As the tooth whitening products commonly used contain or release at least 3% hydrogen peroxide, Mrs. Bonino concluded that the use of such products by dentists and the public was not permitted.

The Scientific Committee on Cosmetic Products and Non-food Products intended for Consumers (SCCNFP) reviewed the safety of hydrogen peroxide in tooth-whitening products following the request to increase the permitted level in Annex 3 of Directive 76/768/EEC from 0.1 to 3.6%. In the plenary meeting of 17th February 1999, the SCCNFP adopted the opinion that it would be inappropriate to provide products with more than 0.1% hydrogen peroxide as cosmetic products. This decision was due to the fact that the contra-indications and warnings necessary for products with a higher concentration of hydrogen peroxide were found incompatible with the nature of a cosmetic product.

Therefore, at present tooth-whiteners containing or releasing more than 0.1% hydrogen peroxide cannot be marketed as cosmetic products within the member states of the EC.

Tooth Whiteners as Medical Devices

According to Article 1 of the Council Directive 93/42/EEC of 14th June 1993, materials intended by the manufacturer to be used for the purpose of treatment or alleviation of disease and which do not achieve their principle intended actions by pharmaceutical, immunological or metabolic means are medical devices. Therefore, tooth-whitening products intended by the manufacturer to be used for tooth discolourations caused by disease such

as pulp necrosis or by tetracycline medicamentation are medical devices. With this as a basis, it is possible to challenge Mrs. Bonino's statement that all tooth-whitening products are cosmetics by taking legal measures against the local Competent Authorities.

This opinion is neither shared by the Notified Bodies (institutions certifying compliance of manufacturers with EC regulations regarding a quality management system for the development and the production of medical devices) nor by the local Health Authorities which have to adopt Mrs. Bonino's view. This may result in further court actions similar to those already ongoing:

In the UK in 1998, the High Court ruled that a tooth-whitener product is a medical device and that the Department of Trade and Industry (DTI) was wrong in ban its use. The DTI appealed and on 1st July 1999, the Court of Appeal overturned the previous High Court ruling. Leave was then being thought from the House of Lords to appeal against the later ruling. In summer 2001, the House of Lords ruled that a tooth-whitener product is a cosmetic product. It can thus not be marketed in the UK without the risk of legal action.

In Germany, the Verwaltungsgericht Düsseldorf (16 K 6063/99) ruled that a tooth whitener is considered a medical device. The Competent Authority (Bezirksregierung Düsseldorf) appealed and the decision which had been expected for fall 2001 has now been postponed to spring 2002. Both parties of this dispute indicated to appeal if not successful.

As long as the European Commission do not reconsider their unfortunate and wrong statement of 1996, the dispute will go on until the European Court comes to a ruling.

6 Illuminé™ Tooth Whitening System

The Illuminé™ Tooth Whitening System is a complete concept for external bleaching that covers both in-office and at-home bleaching with different peroxide concentrations (Figure 6) to gain best results according indications, safety, and efficiency.

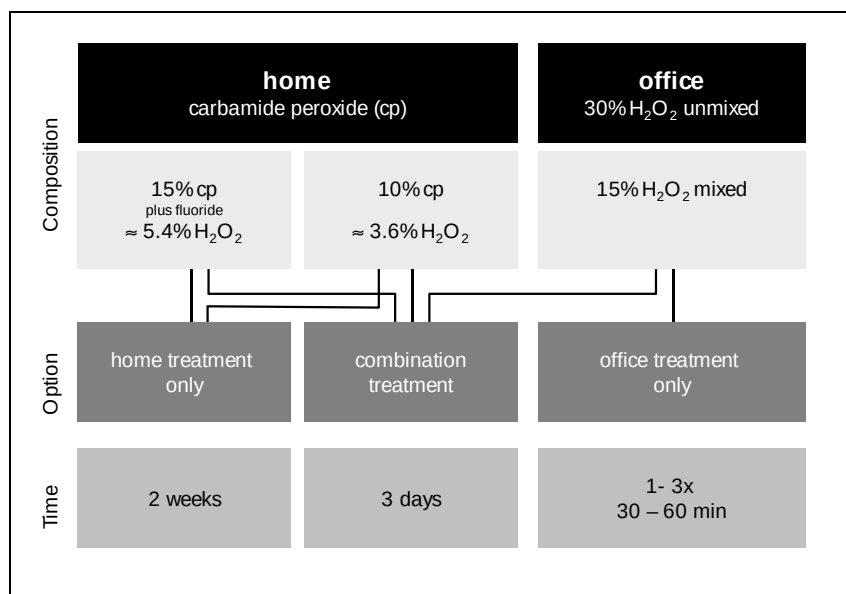


Figure 6 Overview of the Illuminé™ Tooth Whitening System.

Illuminé home Tooth Whitening Gels may be used alone or following treatment with an in-office tooth whitener.

Illuminé office In-Office Tooth Whitener is recommended as a pre-treatment boost to Illuminé home Tooth Whitening Gels or as a stand-alone treatment completed in 1 to 3 office visits. If used as a boost to Illuminé home, the take-home regime may be abbreviated to a 3-day treatment.

The Illuminé Tooth Whitening products, their presentation forms, and the product information (separate booklets for dentist, patient, and dental technician) have been specifically developed to meet the requirements set by the European Commission for Medical Devices.

6.1 Indications and Contraindications

Indications

1. Tooth discolouration caused by:

- Staining from foods, drinks, and tobacco with penetration into the tooth substance
- Age-dependent degenerative changes
- Tetracycline (first and second grades) or minocycline medicamentation
- Fluorosis, especially brown pigmentation
- Pulp necrosis and/or endodontic treatment
- Masking of enamel mottling
- Genetically determined dark teeth
- Whitening of discoloured teeth prior to restorative and/or prosthodontic measures, e. g. veneering

The best results are with patients whose teeth are discoloured to yellow, orange, or light brown.

Contraindications

- Use during pregnancy or lactation.
- Known allergy to hydrogen peroxide or other ingredients of the products.
- Extrinsic stains which can easily be removed by professional tooth cleaning and which can be prevented by thorough oral hygiene.
- Use in heavy smokers unless they refrain from smoking while wearing the tray.

6.2 Interactions with Dental Materials

Existing tooth coloured restorations may not match the lighter shade of teeth after the treatment and may need to be replaced.

The Illuminé products should be used before the placement of composites, veneers or crowns, in order to maintain a close match of tooth colour. We also recommend that the patient wait a minimum of two weeks after the treatment for the tooth discolouration to stabilise before performing anterior restorations.

Some old restorations (e.g. amalgams) may leave dark stains in the tray. This is normal and harmless.

6.3 Tray Manufacturing

A well fitting tray with a proper gingival seal and margins just away from the gingiva is essential to reduce irritation of the gingiva during the whitening procedure to a minimum.

For tray fabrication, information on which teeth are planned to be treated as well as the whitening technique (home treatment only or office treatment) should be available. For communication between clinician and technician, a form (Figure 7) is supplied on the last page of the "Instructions for tray fabrication" booklet.

The tray for Illuminé office (the gel reservoir of which is larger than that of the tray designed for sole home application) may also be used for short-term subsequent treatment with Illuminé home.

Generate Stone

Pour the disinfected, rinsed impression with dental stone.

Trim the stone cast so that the base is parallel to the occlusal plane of the posterior teeth and that the base extends 2-4 mm past the gingival border.

Tray Fabrication

For tray fabrication, please also see illustration (Figure 7).

Illuminé™

Instructions for Tray Fabrication

Patient: Mr Teeth

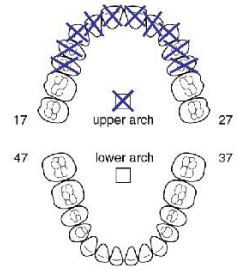
Dentist: Dr Bleach

Date: 2001-12-06

Whitening Technique:

☒ Illuminé home

☐ Illuminé office or Illuminé office & home

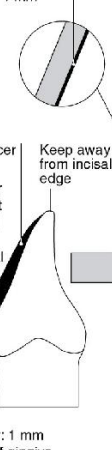


Teeth and arch to be treated are marked by a cross 

Spacer thickness:

Illuminé home only

0.5 - 1 mm



Thicker layer at central and cervical region

Keep away from incisal edge

Illuminé office
Illuminé office & home

3 - 4 mm



gingival "seal"

Spacer: 1 mm short of gingiva

Tray: 0.5 mm short of gingiva

Note: Gel reservoir is created only for teeth to be treated

Figure 7

Creating the Reservoirs

1. Once the stone model has dried to an effective hardness apply an acrylic spacer (e. g. Triad¹ Gel) to the teeth on the model, thus creating reservoirs in the gel tray.
2. Apply the spacer only to teeth of aesthetic value.
3. Stay approximately 1 mm from the gingival margin when applying the spacer.
4. Do not cover any interproximal areas.
5. Do not apply spacer to occlusal surfaces or incisal edges.
6. Apply a spacer to the facial surfaces of the teeth to be whitened.

For treatment with Illuminé home tooth whitening gels alone, the thickness of the spacer is approx. ½ to 1 mm.

For treatment with Illuminé office or a combination treatment with Illumine office and home, the thickness of the spacer is 3-4 mm.

Note: If the tray will be used for an in-office procedure alone or an in-office procedure in combination with short-time treatment with Illuminé home tooth whitening gels, the thickness of the spacer is increased according to the directions for use of the respective product.

Wait until spacer has set or light-cure spacer, respectively.

7. Wipe the cured spacer surfaces with a 7. gauze dampened with alcohol to remove the slightly tacky surface that remains on the cured acrylic spacer.

Forming the Tray

1. Use a medium thick heat/vacuum sheet² for tray fabrication.
2. Place the vacuum sheet (pebble finish towards the stone model) on a heat/vacuum tray-forming machine.
3. Soften the vacuum sheet until it sags 2 to 5 cm or as directed by the Manufacturer.
4. Engage the vacuum, and slowly lower the heated gel tray onto the stone model to avoid generating wrinkles and folds.
5. Allow the sheet ample time under vacuum for good retention and definition.
6. Allow the sheet to cool prior to trimming.

Trimming the Tray

1. Remove the gel tray from the stone model.

¹ DENTSPLY DeTrey, Dreieich (D).

² Erkodur (clear), 0.8 mm thickness, Reorder # 521108 (Erkodent[®], D-Pfalzgrafenweiler)

2. Using scissors trim the tray approximately 2-3 mm beyond the teeth.
3. Trim and refine the remaining portion with smaller, precision scissors (Scallop around the interdental areas).
4. Trim the tray approximately 1/4 - 1/2 mm short of the gingival margin.
5. Place the trimmed tray back onto the stone model to verify extensions.
6. Finish margins with rotary instruments or slightly flame polish tray edges.
7. Wash and disinfect the whitening tray. Dry thoroughly.
8. Place in storage case or other suitable container and deliver to dentist.

7 Illuminé home

7.1 Product Description

Illuminé home Tooth Whitening Gels may be used alone or following treatment with an in-office tooth whitener. When used as following treatment the same tray of the prior Illuminé office treatment can be used.

Illuminé home Tooth Whitening Gels contain the active ingredient of carbamide peroxide, which has shown to be most effective for the treatment of tooth discolourations at home.

Illuminé home 10% Tooth Whitening Gel contains 10% carbamide peroxide, releasing H_2O_2 in a concentration of about 3.6%.

Illuminé home 15% Tooth Whitening Gel contains 15% carbamide peroxide, releasing H_2O_2 in a concentration of about 5.4%, and in addition sodium fluoride.

7.2 Composition and Working Mechanism

Illuminé home 10% and 15% are colourless tooth whitening gels for nightguard or day-time home treatment comprising carbamide peroxide as active bleaching ingredient. The composition is shown in Figure 8.

Illuminé™: Tooth Whitening System Illuminé™ home 10% & 15% • Nightguard/ day-time home bleaching gel • 10% / 15% carbamide peroxide equivalent 3.6% / 5.4% H₂O₂ • Gelating agent Carbomer (modified polyacrylic acid) • Sodium hydroxide to buffer pH to 5.7-6.5 • Illuminé home 15% comprises 0.22% sodium fluoride • Mint flavor • Solvent glycerine	
--	---

Figure 8 Composition of Illuminé home 10% and 15%.

The gelating agent used within both formulations is Carbomer which is modified polyacrylic acid. The pH of this polyacid is buffered to 5.7 – 6.5 with sodium hydroxide. The formulation provides good adherence of the gel on the tooth surface. Peroxide is released almost completely after two hours (Christensen, 2001).

Additionally, the 15% formulation comprises sodium fluoride to reduce sensitivity.

7.3 Clinical Investigations

Safety and performance of the two carbamide peroxide based tooth whitening gels for dentist-monitored home application, marketed by DENTSPLY DeTrey under the brand Illuminé home, were investigated in 3 separate formal investigations.

7.3.1 Clinical investigation of Illuminé home 10% by Swift et al at UNC (1997)

The material used in the investigation is identical to the formulation of Illuminé home 10%. Design, method, and material of the investigation are summarised in Figure 9, the findings are summarised in Figure 10 and Figure 11.

The investigators conclude that the test material was an effective agent for lightening of discoloured teeth.

Illumine™ home 10%: UNC Clinical Investigation (1997)

Investigator/s	Swift et al
Design	Double-blind controlled investigation
Number of patients	29 patients
Control materials	Placebo gel
Method	50% of patients treated with test material, 50% of patients treated with placebo gel for 14 days, then switch of region and further treatment for 14 days Individual trays Thickness of reservoir: 0.5mm Shade determination with Vita Lumin guide, pre- treatment, 2 weeks, 4 weeks, 3 + 6 mths post-treatment

Figure 9

Illumine™ home 10%: UNC Clinical Investigation

Shade Changes after 2 Weeks

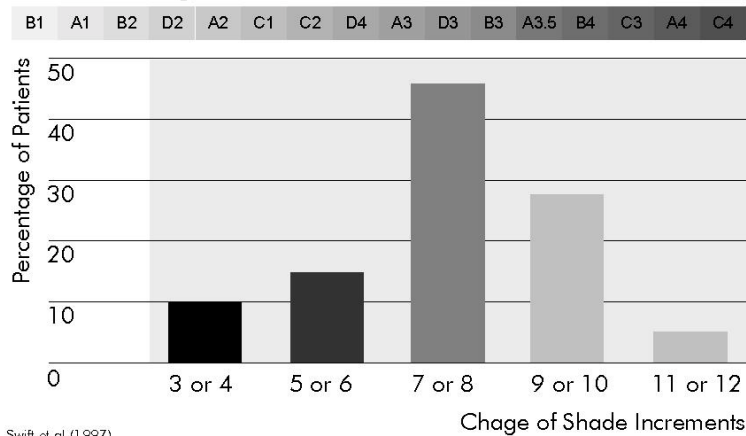


Figure 10

Illumine™ home 10%: UNC Clinical Investigation (1997)

Other findings

- Shade changes in placebo group occurred in 35% of the cases.
- Whitening remained efficacious after 3 months in 97% of the cases and after 6 months in 90% of the cases.
- Transient tooth sensitivity was 17% in placebo group and 7% with Illuminé home 10%

⇒ Effective agent for lightening discoloured teeth

Figure 11

7.3.2 Clinical investigation of Illuminé home 10% by Barnes et al at the University of Maryland (1998)

The material used in the investigation is identical to the formulation of Illuminé home 10%. Design, method, and material of the investigation are summarised in Figure 12, the findings are summarised in Figure 13 and Figure 14.

The investigators concluded that the test material when administered under the supervision of a dentist is an effective whitening agent.

Illumine™ home 10%: University of Maryland Clinical Investigation (1998)

Investigator/s	Barnes D M et al
Design	Double-blind clinical trial
Number of patients	61 patients
Control materials	placebo gel
Method	50% of patients treated with test material, 50% of patients treated with placebo gel for 14 days Individual trays Thickness of reservoir: 0.5-1mm Shade determination with Vita Lumin guide, pre- treatment, 14 days, 3 and 6 months post-treatment

Figure 12

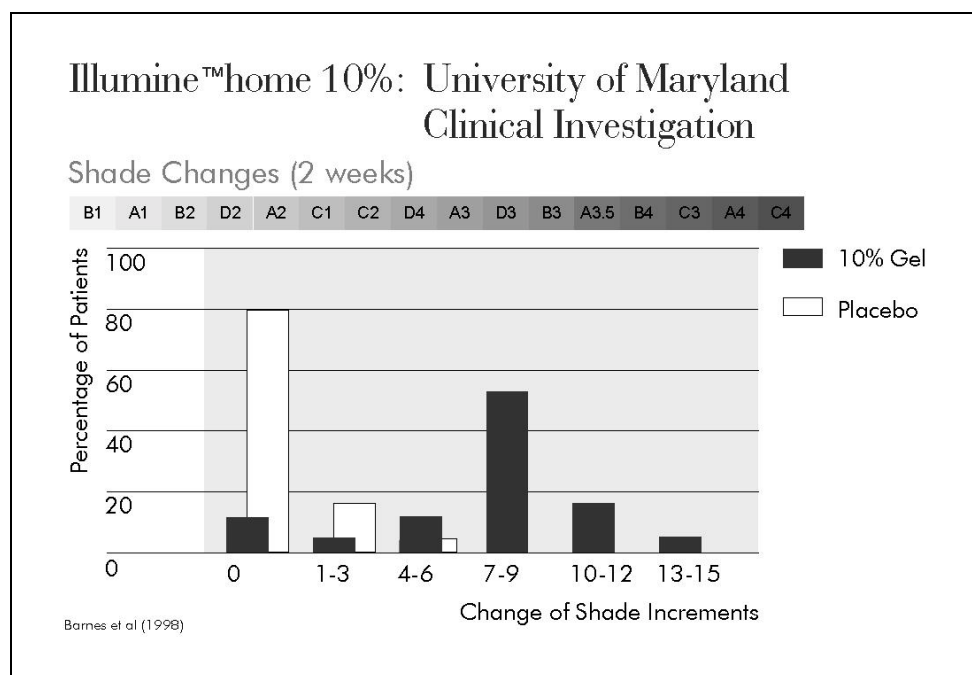


Figure 13

Illumine™ home 10% : University of Maryland Clinical Investigation (1998)

Other findings

- Whitening remained efficacious at 3 months in at least 76% of the cases and at 6 months in at least 64% of the cases.
- Transient tooth sensitivity and/or gingival sensitivity occurred in approx. 2/3 of the patients.
- No significant changes in gingival condition.

⇒ Effective and safe tooth whitening system

Figure 14

7.3.3 Clinical investigation of Illuminé home 10% and 15% by Kihn et al at the University of Maryland (2000)

The whitening gels investigated in this clinical trial are identical to the formulations of Illuminé home 10% and Illuminé home 15%.

Design, materials, and methods used in the investigation are summarised in Figure 15, the outcome is summarised in Figure 16 and Figure 17.

Illumine™ home 10% + 15%: University of Maryland Clinical Investigation (2000)

Investigator/s	Kihn PW et al
Design	Double-blind clinical trial
Number of patients	57 patients
Method	50% of patients treated with 15% gel, 50% of patients treated with 10% gel Individual trays Thickness of reservoir: 0.5-1mm Treatment time: 14 days (≥ 4h/d) Shade determination with Vita Lumin guide, pre-treatment, 1 week, 2 weeks after begin of treatment, 2 weeks post-treatment

Figure 15

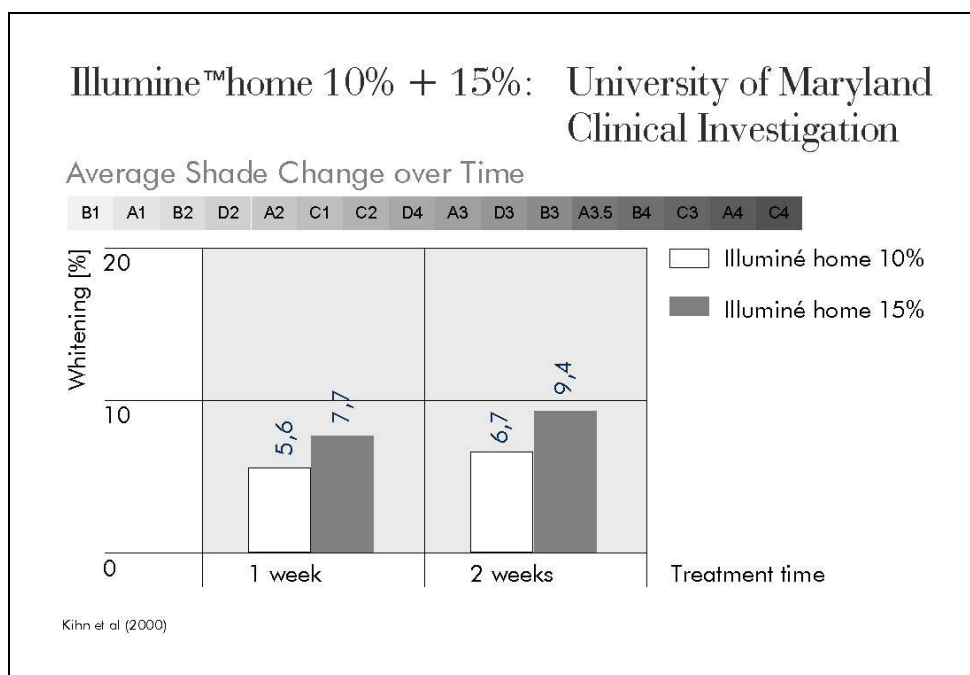


Figure 16

Illumine™ home 10% + 15%: University of Maryland Clinical Investigation (2000)

Other findings

- At one week, no significant difference in shade change with 10% and 15% gels.
- With the 15% gel, a significantly more intense whitening was achieved after 2 weeks of treatment and 14 days after end of treatment.
- No significant difference in level of tooth sensitivity between the two groups.

⇒ Both gels offer an effective whitening treatment.
The 15% gel offers a more intensive colour change.

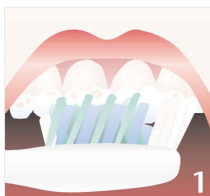
Figure 17

7.4 Step-by-Step Instructions



Prior to use of the Illuminé products, it is mandatory to read the respective Directions for Use. Here you will also find the complete instructions for use, information on precautions which have to be taken prior to treatment and warnings to be considered.

Illumine™ home: Step-by-Step Patient Instructions

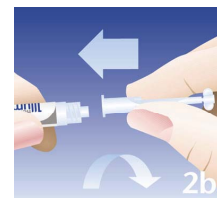


Brush and floss teeth
prior to wearing the
tray.

Illumine™ home: Step-by-Step Patient Instructions

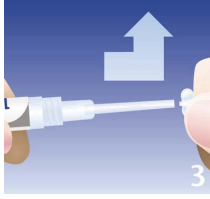


Prior to first use of syringe,
remove cap.



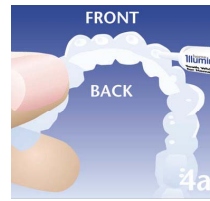
Fix applicator provided
on syringe.

Illumine™ home: Step-by-Step Patient Instructions

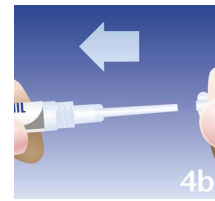


Open applicator by breaking off tip (retain tip to close applicator after use of syringe).

Illumine™ home: Step-by-Step Patient Instructions



Place small amounts of gel towards facial side of teeth to be treated.



Close applicator on syringe.

Illumine™ home: Step-by-Step Patient Instructions

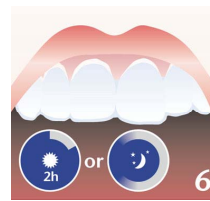


Insert gel tray in the mouth over the teeth



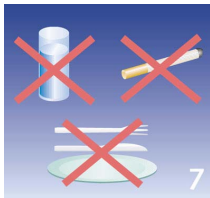
Wipe excess material from the gums or tissues with finger or tooth brush.

Illumine™ home: Step-by-Step Patient Instructions



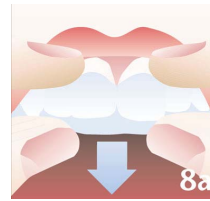
Wear the tray throughout the night or as directed (a minimum of 2 hours is suggested).

Illumine™ home: Step-by-Step Patient Instructions



Do not eat or drink anything or smoke while wearing the tray.

Illumine™ home: Step-by-Step Patient Instructions



After treatment, remove tray.



Rinse your teeth. Brush away any remaining gel.

Illumine™ home: Step-by-Step Patient Instructions



Clean the gel tray with warm water and a tooth brush.



Dry tray thoroughly and store in tray holder.

8 Illuminé office

8.1 Product Description

Illuminé office is unique in both technique and formulation and makes use of a new chemical concept for the controlled release of hydrogen peroxide.

Illuminé office is a 15% hydrogen peroxide-based treatment which will provide with significantly noticeable whitening results in 30 minutes. The process requires no light or heat activation.

Illuminé office is recommended as a pre-treatment “boost” to Illuminé home Tooth Whitening Gel, or as a stand-alone treatment, completed in 1 to 3 office visits. If used as a boost to Illuminé home, the take-home regimen may be abbreviated to a 3-day treatment.

Each kit contains two (2) syringe sets and an applicator tip for each. Each syringe set comprises one syringe containing a 30% hydrogen peroxide solution (syringe A) and one powder syringe (syringe B) with an attached stopcock. Each syringe set contains enough material to whiten 1 arch.

The hydrogen peroxide solution and the gelating powder are separated in two syringes to maintain stability during storage. The contents of the syringes A (hydrogen peroxide) and B (powder) are mixed according to the step-by-step instructions directly before administration. The mixed 15% hydrogen peroxide bleaching gel is applied in the custom-fitted tray. After setting of the gel to a rubbery semi-solid (setting time: 30 to 60 seconds) the tray is seated on the teeth. Due to the semi-solid consistency and the good adherence on the tooth surface migration of the material can be avoided. Therefore, gingival isolation should not be required if the instructions are followed, and a well-fitting bleaching tray has been prepared with adequate (3 – 4 mm depth) reservoirs for each tooth to be bleached.

8.2 Composition and Working Mechanism

Syringe A contains: 30% hydrogen peroxide

Syringe B contains: Poly (Methyl Vinyl Ether/Maleic Anhydride) mixed calcium/sodium salts, titanium dioxide

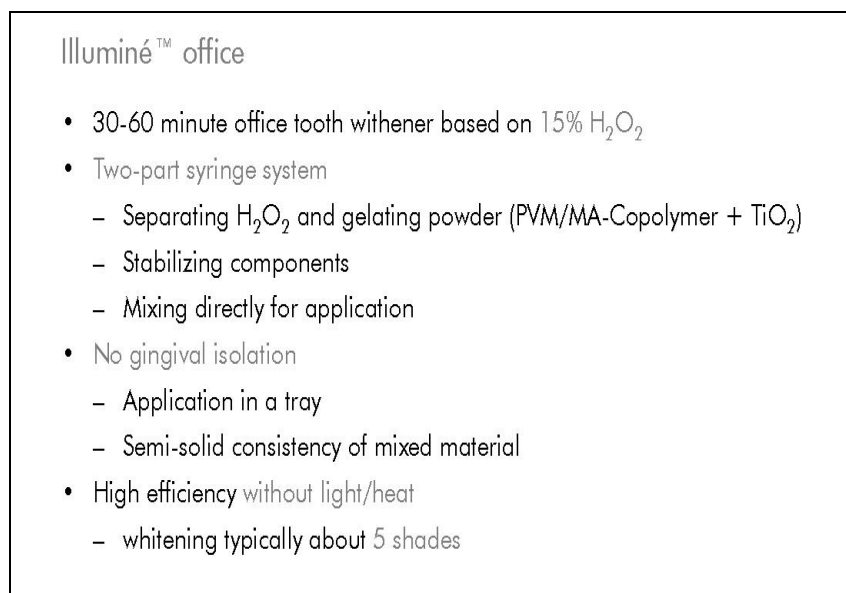


Figure 18 Unique performance of the Illuminé office bleaching system.

Illuminé office has a unique rubbery semi-solid consistency which allows safe administration without gingival isolation, and improves comfort and economy of in-office bleaching. The advantageous consistency is achieved with mixed sodium/calcium salts of poly(methyl vinyl ether/maleic anhydride) which is a copolymer (PVM/MA-copolymer) and exhibits gelating properties. This copolymer is part of the powder in syringe B. When mixed with the hydrogen peroxide solution that contains 70% water, the copolymer absorbs the water and swells. Setting to the semi-solid is due to the hydration reaction. It is not possible to combine the powder with the hydrogen peroxide ahead of time as the mixed material will form a skin and can no longer be extruded from the syringe. The mixture progressively releases the peroxide over time. Therefore, the products must be mixed at the point of use.

Additionally, the PVM/MA-copolymer buffers the pH of the hydrogen peroxide solution (pH 3) to be between 5.6 and 5.9 in the mixed material. An enamel surface study was conducted by scanning electron microscopy which indicates that exposure to the final mixed product for up

to 90 minutes will NOT demineralise the enamel and effect the tooth surface structure (see In-vitro data, Chapter 8.3).

The PVM/MA-copolymer provides the good adherence of the rubbery semi-solid to the tooth surface which is necessary for optimal release of the hydrogen peroxide to the tooth and best bleaching efficiency.

Titanium dioxide (TiO₂) causes the opaque white colour of the mixed gel which makes optical control of proper seating of the gel on the teeth more comfortable.

8.3 In-Vitro Data

Evaluation of the Enamel Surface Morphology in Teeth Treated with Illuminé office by Sherman J, DENTSPLY Professional

8.3.1 Summary

The study was conducted to determine if the Illuminé office In-Office Tooth Whitener has any effect on tooth surface morphology when placed directly on the tooth surface for designated periods of time. Mixed product was placed directly on the surface of extracted human teeth for 30 minutes, 60 minutes, 90 minutes, or a series of three 30-minute treatments. Scanning electron microscopy was used to evaluate surface morphology changes post-treatment compared to untreated tooth surface. The results of the study suggest that Illuminé office does not produce significant morphological changes in the surface of a tooth when administered for up to 90 minutes or when administered for a total of 90 minutes through three individual 30-minute treatments in an in vitro environment.

8.3.2 Methods

Application of Illuminé office

Extracted human incisors were treated on the longitudinal half of the anterior surface with the mixed bleaching gel. The material was placed directly on the tooth surface and allowed to set up. A dab of Triad Gel was placed on the posterior of each tooth and light-cured to designate the treated side of the tooth. The remaining half of each tooth served as an

untreated control for the tooth. The teeth were partially and intermittently submersed in deionised water and maintained at 37°C for the duration of the treatment. Treatment times were 30 minutes, 60 minutes, 90 minutes or a series of three 30-minute treatments at 24 hour intervals. The material was gently removed with gauze and the teeth were placed in labelled containers of deionised water.

Positive control

Etching gel was applied to the surface of one tooth for two minutes. The tooth was then placed in a labelled container of deionised water.

Evaluation

Upon completion of treatment, the teeth were sent to DENTSPLY Caulk for surface morphology examination by scanning electron microscopy (SEM). Treated and untreated areas of each tooth were visually examined and photographed at magnification ratios of 2500:1 and 5000:1.

8.3.3 Results

The SEM photographs suggest that Illuminé office does not produce significant morphological changes in the surface of a tooth when administered for up to 90 minutes or when administered for a total of 90 minutes through three individual 30-minute treatments in an in vitro environment (Figure 19 - Figure 22). In difference to the treatment with Illuminé office, after etching teeth of the positive control group exhibit typical etching pattern of the enamel surface (Figure 23).

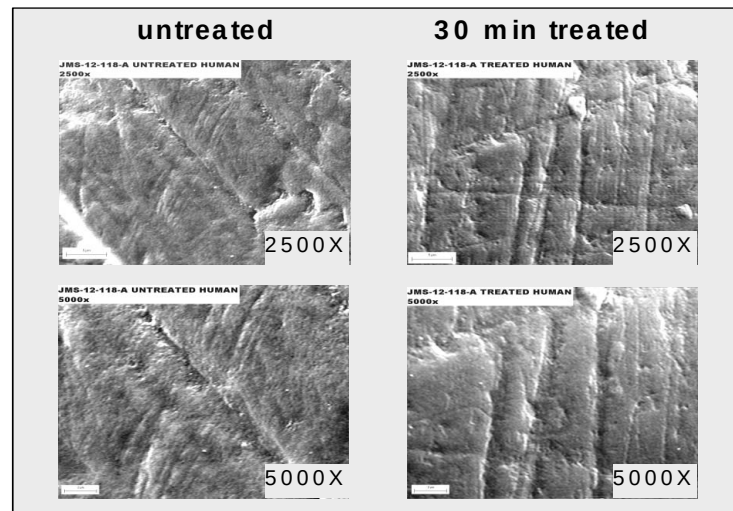


Figure 19 Scanning electron microscopy photographs of untreated teeth and of teeth treated with Illuminé office for 30 min.

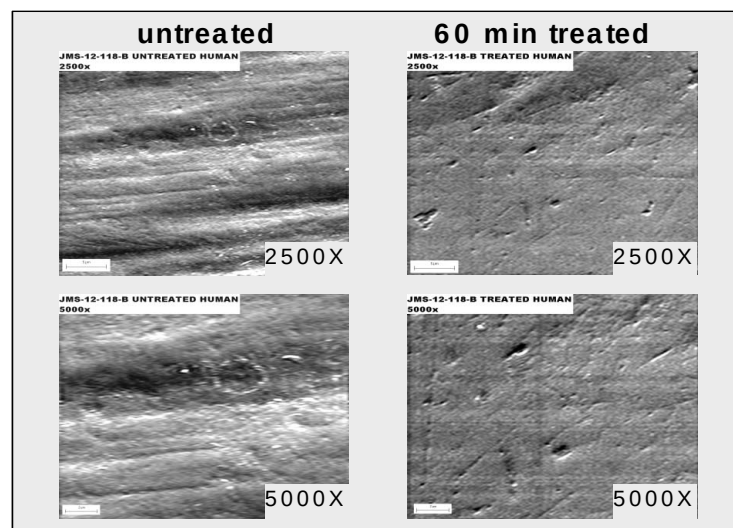


Figure 20 Scanning electron microscopy photographs of untreated teeth and of teeth treated with Illuminé office for 60 min.

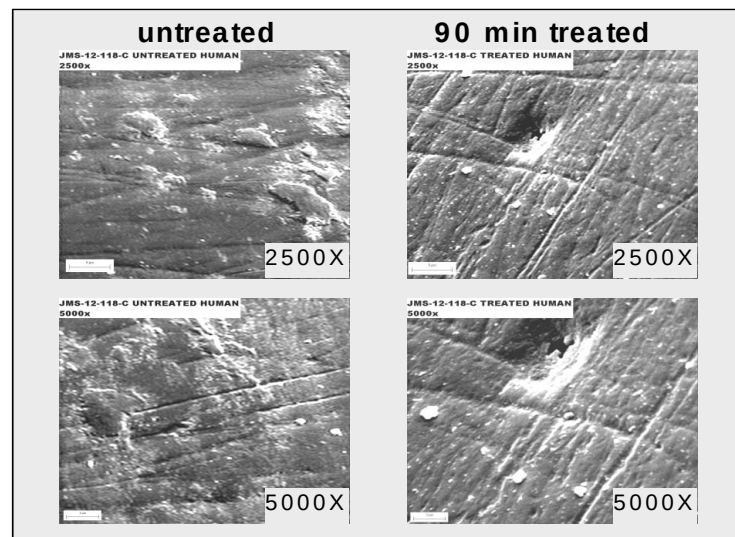
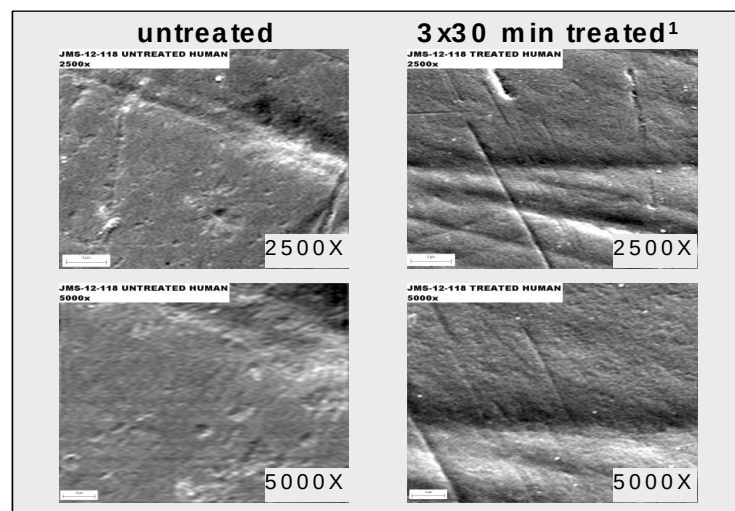


Figure 21 Scanning electron microscopy photographs of untreated teeth and of teeth treated with Illuminé office for 90 min.



¹ Interval of 24 h

Figure 22 Scanning electron microscopy photographs of untreated teeth and of teeth treated with Illuminé office for 3 x 30 min with an interval of 24 h.

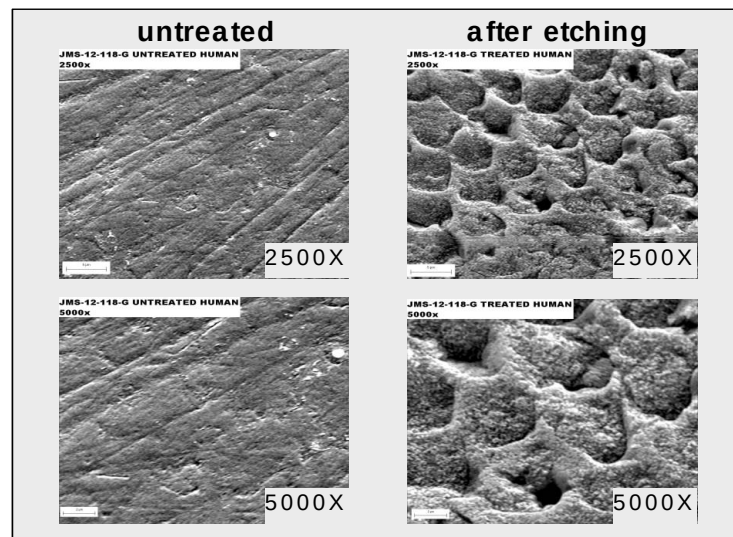


Figure 23 Scanning electron microscopy photographs of untreated teeth and positive control after etching for 2 min.

8.3.4 Conclusion

Under in vitro conditions the morphology of the enamel surface is not significantly altered when treated with Illuminé office up to 90 min.

8.4 Clinical Investigations

Safety and performance of the professional in-office tooth-whitening product marketed by DENTSPLY DeTrey under the brand Illuminé office was investigated in two separate formal clinical investigations and one internal user evaluation. When used as a stand-alone treatment and for an application time of 30 minutes, the average whitening effect achieved in the investigations referred to was 3.4 vs. 5.8 vs. 7.2 shades (measured at the Vita Lumin shade scale).

8.4.1 A Clinical Study Evaluating the Efficacy of a New Chairside and Take-Home Bleaching System – Final Report, January 27, 2000 by Bardwell D, Papathanasiou A, Tufts University Dental Clinic

Objectives: To evaluate the effectiveness and safety of a 15% hydrogen peroxide in-office whitening product followed up by home application of a 10% carbamide peroxide whitening gel.

Materials and Method: The upper anterior teeth of 24 patients with a shade no lighter than A3 were selected. Shades were assessed using a Vita Lumin Shade Guide. The in-office whitening product (used for 30, 45, and 60 minutes) and the home whitening gel were applied in custom-made trays. Shade recording was done prior to application, immediately after in-office treatment, 24 hours after in-office treatment and 24 hours, 72 hours, and 7 days after home treatment.

Results: Whitening could be attained quickly with the in-office system and was enhanced by subsequent home application of the 10% carbamide gel.

The final result was slightly different for the 30-minute, 45 and 60-minute in-office treatment (Table 1).

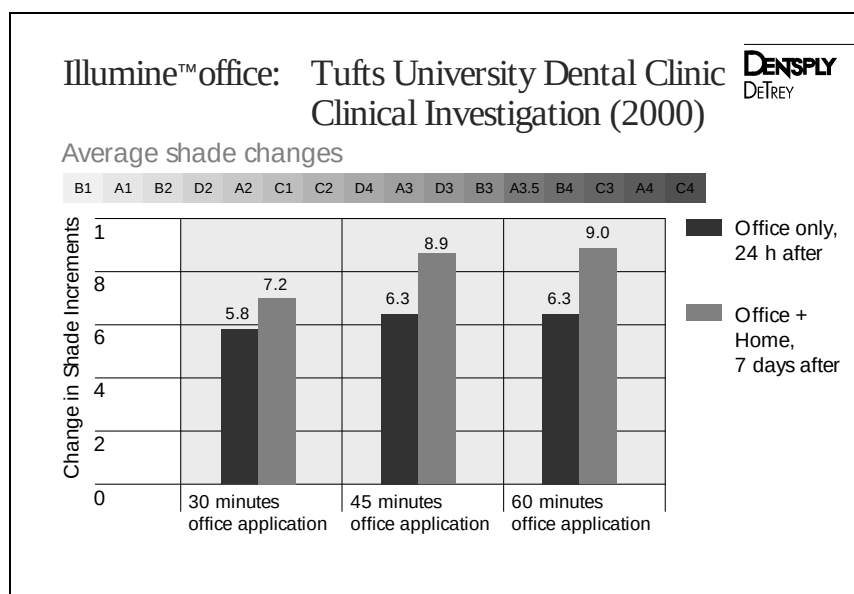


Table 1

50% of the patients treated experienced tooth sensitivity which improved fast and did not return for any patients at completion of the investigation.

8.4.2 Clinical Evaluation of a 15% In-Office Hydrogen Peroxide Tooth Whitening Touch Up Agent - Updated Report April 24, 2000 by Kihn P W, Barnes D M, Adachi E, The University of Maryland Dental School

Objectives: To investigate the performance when used as a "touch up" treatment for previously whitened teeth

Materials and Methods: 31 patients with previously whitened teeth were treated with Illuminé office applied in a custom-made tray (where available, the existing whitening trays were used). For 10 patients, the application time was 30 minutes, for 11 patients it was 45 minutes, and for another 10 patients it was 60 minutes. Shade determination was carried out with a Vita Lumin shade guide and was documented by colour transparencies at 1:1 magnification:

Pre-application,
Immediately post-application,
72 hrs post-application.

Results: Of the 31 patients who began the study, 2 did not return for the 72-hour recall and were excluded from the analysis as were 2 patients presenting with shades lighter than B1.

Frequency distribution for shade change of the remaining 27 patients is given in Table 2.

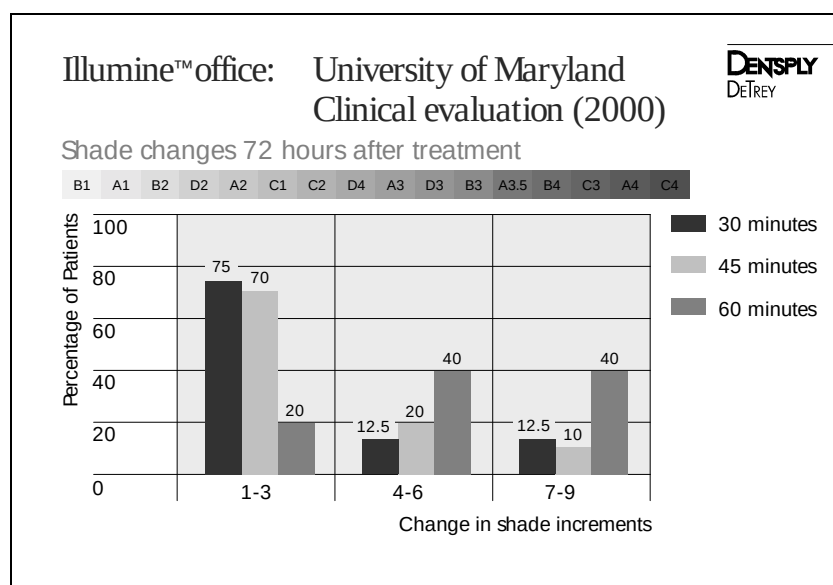


Table 2

The average shade changes are given in Table 3. The shade change for the 30-minute treatment was 3.4 at 72 hours post-treatment.

Average shade changes			
	Minutes		
	60	45	30
Immediate post-op	4.9	2.3	2.7
72-hrs post-op	5.5	3.1	3.4

Table 3

Tooth sensitivity occurred in the majority of all cases (Table 4), but there was only 1 case with lingering tooth sensitivity at the 72-hour recall.

Side effects: Tooth sensitivity	
None	11/31
During treatment	8/31
Day of treatment	11/31
Day after treatment	10/31
2 days after treatment	2/31
3 days after treatment	1/31

Table 4

7 patients experienced mild gingival burns, i. e. a whitening of the tissue, which left behind an erythematous area from contact with the bleaching material. In 6 of these cases, the problem was associated with an ill-manufactured tray.

6 of the patients reported a burning sensation of the gingiva during treatment which disappeared after tray removal.

Conclusions:

- The test material proved to be an efficient agent for rewhitening.
- Proper tray fabrication is important for the prevention of gingival burns.

- Side effects were mild and manageable by both the clinician and the patient.

8.4.3 In-House Whitening Case Study FP 084 – Report February 4, 2000 by Sherman J, DENTSPLY Preventive Care

Objectives: To evaluate the effectiveness of Illuminé office for whitening teeth when applied for 15 or 30 minutes

Materials and Methods: 12 subjects were divided in 2 treatment groups (1 for 15-minute, 1 for 30-minute application times). Shade evaluation with Vita Lumin Shade Guide was carried out prior to application, immediately after application, and 24 hours after application. The in-office whitening product was applied in custom-made trays.

Results: Both the 15-minute and the 30-minute treatments were effective to whiten teeth. However, the 30-minute result proved to be superior (Table 5).

Illuminé office: Clinical in-house investigation (DENTSPLY Preventive Care)	
	Average change from baseline to 24 h recall
Treatment time	Change
30 minutes	7.2 ± 2.0
15 minutes	5.0 ± 2.0

Table 5

No patient complained of sensitivity during treatment. One patient reported significant post-treatment sensitivity, but by the 24-hour recall the sensitivity was gone. 5 patients experienced isolated minor gingival irritation that had resolved by the 24-hour recall.

Conclusions: Significant tooth whitening can be achieved with Illuminé office as a stand-alone treatment.

8.5 Step-by-Step Instructions

Initial Consultation

1. Review the patient's medical and dental history.
2. Perform an intraoral examination of the, soft tissue, periodontal, and teeth health.

3. Inform the patient that depending on the nature of the stain, an extended treatment may be required to attain the desired effect.
4. A full prophylaxis (using Nupro Prophy Paste) and fluoride treatment is recommended before starting the bleaching process.
5. The complete procedure should be discussed with the patient, reviewing any potential problems and side effects.
6. Inform the patient that any existing tooth coloured restorations may not match the lighter shade of teeth after the treatment and may need to be replaced.
7. Use a suitable shade guide, e. g. Biodent3 or Vita4 Lumin Vacuum shade guide, to make a shade determination at baseline. Enter the determined shade into the patient's record.

Take Impression

Make an alginate or elastomer impression of the arch to be treated (It is highly recommended that the teeth be treated one arch at a time, so that the patient can see the changes.)

Tray Fabrication and Communication with Dental Laboratory

see Chapter 6.2

Gingival Isolation

Gingival isolation should not be required if the instructions are followed, and:

- a well-fitting bleaching tray has been prepared with adequate (2-4 mm depth) reservoirs for each tooth to be bleached
- the Illuminé material has been allowed to properly set, assuring that it will adhere to the tooth surface and not migrate, and
- care has been taken during placement in the mouth to assure that the material has not contacted the gingiva.

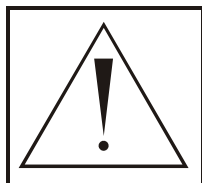
If, however, the instructions cannot be followed, or if edentulous or interdental gingival spaces such as diastemas are present, we strongly recommend that the gingival tissue in

³ DENTSPLY DeTrey

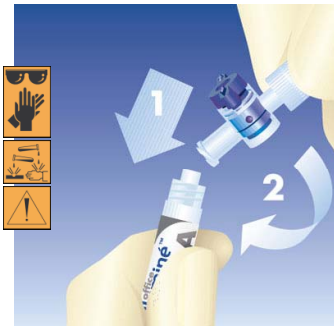
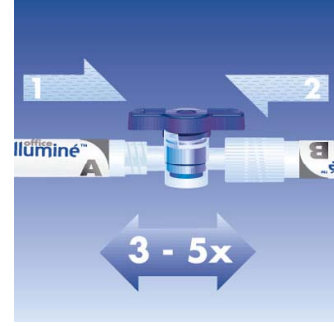
⁴ Vita® is a registered trademark of Vita Zahnfabrik.

question be protected via a petrolatum jelly such as Vaseline®, an isolation resin (paint-on rubber dam), or a conventional rubber dam.

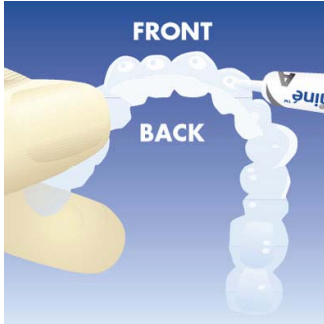
Step-by-Step Instructions for Application of Illuminé office



Prior to use of the Illuminé products, it is mandatory to read the respective Directions for Use. Here you will also find the complete instructions for use, information on precautions which have to be taken prior to treatment and warnings to be considered.

Illuminé™ office: Step-by-Step Instructions  Step 1: Always hold syringe A upright, remove cap, and screw syringe B onto syringe A.	Illuminé™ office: Step-by-Step Instructions  Step 2: Turn valve to "on" position.
Illuminé™ office: Step-by-Step Instructions  Step 3: Mix from syringe A to syringe B 3 - 5 times. Mixed material must end in syringe A.	Illuminé™ office: Step-by-Step Instructions  Step 4: Turn valve to "off" position.
Illuminé™ office: Step-by-Step Instructions  Step 5: Remove syringe B from the upright syringe A.	Illuminé™ office: Step-by-Step Instructions  Step 6: Connect applicator tip to upright syringe A.

Illumine™ office: Step-by-Step Instructions



Step 7:

Extrude a small amount of material into each reservoir.

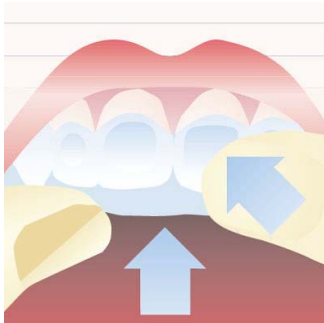
Illumine™ office: Step-by-Step Instructions



Step 8:

Important:
Material must become semi-viscous.

Illumine™ office: Step-by-Step Instructions



Step 9:

Upon required viscosity, seat the tray and press reservoirs.

Illumine™ office: Step-by-Step Instructions



Step 10:

Remove excess material with a scaler.

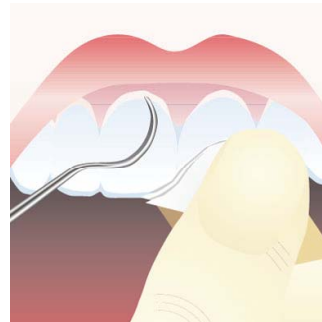
Illumine™ office: Step-by-Step Instructions



Step 11:

Let patient wait for 30 minutes.

Illumine™ office: Step-by-Step Instructions



Step 12:

Remove tray and clean teeth thoroughly.

9 References and Selected Literature

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