Signature Page for VV-TMF-04164 v0.1
Protocol Number: CRO-2025-09-WHT-MS

Reason for signing: Approved	Name: Joanna Woo Role: Safety Approver Date of signature: 23-Sep-2025 12:28:16 GMT+0000
Reason for signing: Approved	Name: Ludjane Carvalho Role: Regulatory Approver Date of signature: 23-Sep-2025 12:48:01 GMT+0000
Reason for signing: Approved	Name: Yun Po Zhang Role: Clinical Manager Date of signature: 23-Sep-2025 13:12:46 GMT+0000
Reason for signing: Approved	Name: John Gallob Role: Principal Investigator Date of signature: 23-Sep-2025 16:09:19 GMT+0000
Reason for signing: Approved	Name: Maria Ryan Role: Executive Approver Date of signature: 23-Sep-2025 18:45:22 GMT+0000

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Colgate-Palmolive Co.

STUDY SUMMARY FOR REGULATORY/SAFETY APPROVAL

Official copies contain "Exact Copy" and "Approved" status in the footer

Approval Required:

- ☐ **Approval by Global Product Safety only**
- ☐ **Approval by Global Regulatory only**
- x **Approval by Both Global Regulatory & Global Product Safety**
- ☐ **No Approval required***

**AS PER REGULATORY AND SAFETY, THIS HUMAN USE PROTOCOL (HUP) MEETS ALL THE CRITERIA FOR EXEMPTION FROM REVIEW BY GLOBAL PRODUCT SAFETY AND GLOBAL REGULATORY TEAM HENCE NO ADDITIONAL REVIEWS AND APPROVALS ARE REQUIRED AND IT IS ELECTRONICALLY SYSTEM APPROVED*

Study originator to provide information by filling in the shaded boxes below

1. **Study Title:**
   Clinical Study to Evaluate the Tooth Whitening Efficacy of a new NextGen in-office whitening system

2. **Study Originator's Contact (name, phone, ext):**
   Melissa Stellitano, tel. #732-258-6594

3. **Product Development Contact (name, phone, ext):**
   Sondes Moussa, 732-258-7624

4. **Type of Study (underline one):**
   Clinical Panel Consumer

5. **Protocol #:**
   CRO-2025-09-WHT-MS DATED SEPTEMBER 5, 2025

6. **Estimated Study Start/End Date:**
   October 2025

7. **Study Location/Country (If home use study in US or Puerto Rico, ensure PPC form is included):**
   Melbourne, FL, USA
   (PPC Forms attached and routed as a separate document)

8. **What Region or Country will the Product(s) tested be marketed:**
   US

9. **If this study requires Regulatory approval, provide reason (ie - claim or clinical endpoint):**
   Claims study for whitening efficacy of NextGen whitening technology
   Clinical Endpoint: Oral Soft and hard tissue Assessment, Safety and Whitening improvements.

10. Washout Products with PDM/Substance Numbers:

Product	PDM/Substance # (or link to pdm)	If Applicable Sample Description
N/A		

11. Test Products with PDM/Substance Numbers:

Product	PDM/Substance # (or link to pdm)	If Applicable Sample Description	Product Code
Colgate Cavity Protection Toothpaste	200000056803/002/000	Study Supply	N/A
Colgate Adult Extra Clean soft-bristle toothbrush	461000000452	Study Supply	N/A
Philips Zoom Professional Whitening Treatment	300000006549/000/000	Control - Light-Activated Whitening - 25% HP gel for in-office use only	Blinded Product
Opalescence Boost PF	300000006551/000/000	Control - 40%HP whitening gel for in-office use only	Blinded Product
Beaming White + Gingival Barrier + CP LED	300000006550/000/000 300000006732/000/000 461000003779	Test - 25%HP gel for in-office use only Gingival Barrier CP LED 20mA	Blinded Product

SYNOPSIS

Study Title: Clinical Study to Evaluate the Tooth Whitening Efficacy of a new NextGen in-office whitening system

Principal Investigator:
Dr. John T. Gallob, DMD
President/Owner Consumer Research Consulting, LLC
5311 Strankman Ave
Las Vegas, NV 89131
e. John.gallob@crc-florida.com
m. 702-885-6984

Examiner: Dr. John T. Gallob, DMD

Study Location/Country: 2717 N Wickham Rd Suite 1, Melbourne, FL 32935, USA

Study Phase: Phase III

Study Products Included for the Clinical Trial:

Group (#subjects)	Study Products	Arm
60	Beaming White - 25%HP Gel + Gingival Barrier + CP LED	Test
60	Philips Zoom Chairside Light-Activated Whitening System - 25% HP Gel	Positive Control
60	Opalescence Boost PF - 40%HP Gel	Positive Control

Objective: To evaluate the Clinical efficacy of a NextGen in-office whitening system compared to commercially available in-office whitening systems.

Study Parameters:

Number of centers: Single-Center
Design: Parallel
Blinding: Examiner-blind
Product assignment: Randomization (RCT)
Number of subjects: 180 male and female
Subject's age group: 18 to 70 years old
Number of test products: Three (3)
Treatment Regimen: In-office whitening application
Number of Exposures (uses): Once
Time-points: Screening/Baseline, immediately post-whitening, Day 7
Duration of Study: Approximately one week
Duration of each Exposure: 45-60 minutes, depending on product assignment
Washout period: None
On-site brushing: Yes

Primary Efficacy Variable(s): Changes in Tooth Color determined by examiner use of Vita Extended Bleachedguide 3D-Master® (29 tabs).

Adverse Reactions:	Monitored via FDA and GCP-ICH guidelines
Plan for data analysis:	ANCOVA
Estimated Start Date:	October 2025

Clinical Study to Evaluate the Tooth Whitening Efficacy of a new NextGen in-office whitening system

Protocol Number CRO-2025-09-WHT-MS

Protocol Date: September 5th, 2025

Sponsored by:

Oral Care Clinical Research
Colgate-Palmolive Technology Center
909 River Road
Piscataway, NJ 08854

Protocol Approval

Signature Page

[eSignature and Date by Colgate-Palmolive Veeva Vault ®]

Dr. Maria E. Ryan, DDS, PhD
Executive Vice President and
Chief Clinical Officer

Date

[eSignature and Date by Colgate-Palmolive Veeva Vault ®]

Dr. Yun Po Zhang, PhD, DDS (hons)
SVP and Distinguished Fellow
Global Oral Care Clinical Studies R&D

Date

Clinical Study to Evaluate the Tooth Whitening Efficacy of a new NextGen in-office whitening system

Protocol Number CRO-2025-09-WHT-MS

Protocol Date: September 5th, 2025

Sponsored by:

Oral Care Clinical Research
Colgate-Palmolive Technology Center
909 River Road
Piscataway, NJ 08855

1. SIGNATURE PAGE

PRINCIPAL INVESTIGATOR APPROVAL AND AGREEMENT

I, the undersigned, have reviewed this protocol and I agree to conduct this protocol in accordance with the Guidelines for Good Clinical Practice, the ethical principles set forth in the Declaration of Helsinki, and with the U.S. Code of Federal Regulations governing the protection of human subjects (21 CFR 50) and the institutional review boards (21 CFR 56).

[eSignature and Date by Colgate-Palmolive Veeva Vault ®]

Dr. John T. Gallob, DMD
Principal Investigator

Date

TABLE OF CONTENTS

I. OBJECTIVE

The objective of this clinical study is to evaluate the clinical efficacy of a NextGen in-office whitening system compared to commercially available in-office whitening systems.

II. STUDY POPULATION

One hundred and eighty (180) subjects, aged 18-70 years, inclusive, will be entered into the study with the expectation that approximately eighteen (18) subjects will complete the study (approximately 10% drop-out rate over the duration of the study). Candidates who have expressed an interest in participating will be selected based on the following criteria:

Inclusion Criteria
Potential subjects must meet **ALL** of the following criteria:

1. Signed Informed Consent Form
2. Male and female subjects aged 18-70 years, inclusive;
3. Good general health and good oral health based on the opinion of the study investigator;
4. All maxillary natural anterior teeth (teeth #6 through #11) must be present;
5. Availability for the duration of the study;
6. Minimum average Vita Extended Bleachedguide 3D-Master shade score of 17 ≥ or darker.

Exclusion Criteria
Potential subjects must **NOT HAVE ANY** of the following conditions:

1. Presence of orthodontic appliances and/or any anterior tooth with a prosthetic crown, veneer, or deemed non-vital;
2. Obvious signs of periodontal disease, rampant caries, or any condition that the dental examiner considers exclusionary from the study.
3. Five or more carious lesions requiring immediate care.
4. Concurrent participation in another oral clinical study.
5. Self-reported pregnant and/or lactating women.
6. History of allergies or sensitivity to tooth whitening products, hydrogen peroxide, personal care consumer products, or their ingredients;
7. Restorations on the teeth to be scored which may interfere with scoring procedures.
8. Have used professional whitening products within one (1) year and/or had dental prophylaxis (professional dental cleaning) within thirty (30) days prior to the start of the study.

III. STUDY DESIGN

1. Configuration

This randomized, examiner-blind, single-center clinical study features a three-cell, parallel-group design to explore the use of a new in-office whitening technology compared to two existing technologies. Patients will be randomized to one of three study groups, and will undergo in-office whitening treatments according to their assigned group.

2. Duration

Subjects' participation in the study will consist of two (2) visits to the clinical research site during approximately 7 days duration of the study: Screening/Baseline, Day 7.

All subjects will be evaluated visually for tooth color shades and conditions of oral tissues at the screening visit. If qualified, subjects will be enrolled and randomized into the study. Baseline visit will be performed on the same day, if time allows. All voluntary candidates will be evaluated for tooth color shades at study entry and the initial tooth shade scores will be recorded as baseline. All qualified subjects will be randomly assigned following a computer-generated master randomization list (online software Sealed Envelope Ltd v.2022) to one of the four treatment groups. Subjects will undergo in-office whitening treatment according to their assigned group. Afterwards, subjects will again have their tooth shade evaluated and recorded, and will be given instructions and hygiene products to use at home, and dismissed. In a subset of subjects (approximately 5/cell), extraoral photos will be taken prior to product application, and after all whitening sessions are completed.

The subjects will be asked to return to the clinic after 1 week, and will again be evaluated for tooth shade, conditions of oral tissues and the occurrence of adverse reactions. Images will again be taken, and a brief questionnaire will be completed to document the patient's experience. After this point, the subject will be dismissed from the study.

3. Master Randomization Plan

Qualifying participants (enrolled) will be randomized using an online software provided by Sealed Envelope Ltd. v.2022. This software employs a block randomization approach with a block size of 6 to ensure balanced allocation to the treatment groups. The randomization sequence will be pre-generated using the 'Create a blocked randomization list' tool. The computer-generated Master Randomization List, which contains random product codes, will be provided to the clinical site prior to the initiation of the study.

Table I. Study flowchart

	Visit 1a	Visit 1b	Visit 2
Visit Procedure	**Screening/ Baseline**	**Immediately after treatment**	**Day 7**
Informed Consent Form/ Privacy Notice	x		
Medical History/Oral Health Questionnaire	x		
Visit Form			x
Review Selection Criteria	x		
Oral Soft and Hard Tissue Assessment	x	x	x
On-site brushing*	x	x	x
Tooth Color Exam (Visual grading)	x	x	x
Photos (in subset only)	x	x	x
In-office whitening	x		
Questionnaire	x	x	x
Randomization, product assignment and instructions	x		

*At each visit, on-site brushing will occur before all clinical shade examinations

IV. STUDY PRODUCTS / TREATMENTS

Study subjects will be randomly assigned to one of the three (3) following products for professional in-office application:

- Beaming White - 25%HP Gel (test)
- Philips Zoom Chairside Light-Activated Whitening System - 25% HP Gel (control)
- Opalescence Boost PF - 40%HP Gel (control)

For daily oral hygiene through the duration of the study all study participants will be provided with:

- Colgate Cavity Protection Toothpaste
- Colgate adult soft-bristled toothbrush

V. PROCEDURES

Visit 1a (Screening/Baseline):

1. Initial Screening and Selection of Subjects

Prospective candidates will report to the clinical facility where they will sign an Informed Consent Form (Appendix II), Privacy Notice (Appendix III), Photo Release (Appendix IV), and complete a Medical History/Oral Health Questionnaire (Appendix V). They will be screened by the study examiner to identify those subjects who meet the inclusion/exclusion criteria. The findings of this initial screening procedure will be recorded on the Initial Screening Form (Appendix VI).

The first 180 subjects who meet the inclusion/exclusion criteria, sign an Informed Consent Form/Privacy Notice and photo release, and complete a health questionnaire will be entered into the study.

2. Oral Soft and Hard Tissue Assessment

All subjects will receive a visual evaluation of their oral soft and hard tissues. This examination will be performed by a study dentist and will include an evaluation of the lips, soft and hard palate, gingival mucosa, buccal mucosa, mucogingival fold areas, tongue, sublingual and submandibular areas, salivary glands, the tonsilar and pharyngeal areas, and teeth. The results of this evaluation will be recorded on the Oral Soft and Hard Tissue Assessment Form (Appendix VII).

3. On-site brushing

Subjects will be asked to perform a supervised on-site brushing with water at each visit immediately prior to having the shade of their teeth graded.

4. Tooth Shade Assessment

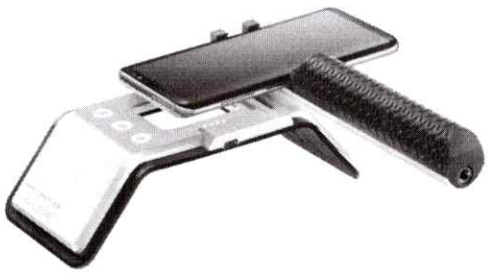
Candidates will be screened by the study examiner to evaluate the tooth shade (color) of the maxillary right central incisor, lateral incisor, and canine, as well as for the maxillary left incisors and canine (teeth numbers 6, 7, 8, 9, 10, and 11). Tooth shade will be assessed by the principal investigator, using the Vita Extended Bleachedguide 3D-Master Shade Guide.

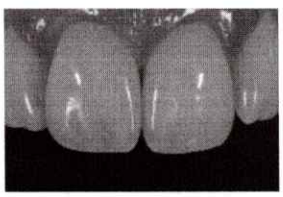
The Vita Extended Bleachedguide 3D-Master includes 29 tabs arranged and numbered by the manufacturer from 1 to 29 (lightest to darkest). Both sets of tabs will be used to assign a shade score to each maxillary anterior tooth. All maxillary anterior teeth must each have a minimum score of a 17 according to the Vita Extended Bleachedguide 3D-Master. Individual tooth shade scores will be recorded on the Tooth Color Examination Form (Appendix VIII).

The methods employed for tooth shade assessments are outlined in Appendix I (Tooth Shade Assessment Guidelines).

5. Extraoral Photos

In a subset of subjects (approximately 5/cell), extraoral photos will be taken using a handheld SmileLite MDP2 system with an attached smartphone. The patient's position will be kept as consistent as possible. Photos will be taken prior to product application, with the retractor in place and no gingival barrier, and will be repeated once more after all sessions are completed and the gingival barrier is removed (again with the retractor in place).





WITH PALETTES

6. Randomization and In-office Whitening

Study subjects will be randomly assigned to one of the three (3) study groups. In-office whitening will then be performed according to the product instructions. This procedure will vary depending on which group the subject is assigned to. An overview of application guidelines for each product is included in Appendix XII.

7. Questionnaire

Subject and provider will complete the relevant portions of a short questionnaire.

Visit 1b: Immediately post-whitening:

1. Oral Soft and Hard Tissue Assessment

All subjects will receive a visual evaluation of their oral soft and hard tissues. This examination will be performed by a study dentist and will include an evaluation of the lips, soft and hard palate, gingival mucosa, buccal mucosa, mucogingival fold areas, tongue, sublingual and submandibular areas, salivary glands, the tonsilar and pharyngeal areas, and teeth. The results of this evaluation will be recorded on the Oral Soft and Hard Tissue Assessment Form (Appendix VII).

2. On-site brushing

Subjects will again be asked to perform a supervised on-site brushing with water for 2 minutes. Afterwards, they will be instructed to rinse with water thoroughly. Shade examination should be done approximately 5 minutes after rinsing, to allow for re-hydration of the tooth surface.

3. Tooth Shade Assessment

The methods employed for tooth shade assessments will be repeated.

4. Extraoral Photos

For the same subset of subjects, a final photo will be taken after whitening is completed, using the same techniques as before (with retractor in place, and no gingival barrier).

5. Questionnaire

Subject and provider will complete the relevant portions of a short questionnaire.

6. Study Product Distribution:

All subjects enrolled in the study will be provided with a soft-bristled adult toothbrush and toothpaste for home use. Subjects will be instructed to brush their teeth twice daily (morning and evening) for two (2) minutes each time with the toothpaste and toothbrush provided. All subjects will be instructed to repeat the same procedure twice daily for the duration of this study.

7. Instruction to Subjects

Subjects will be instructed to use only the products (toothpaste and toothbrush) provided during the study period, and to refrain from using any other oral hygiene products and from routine dental treatment (except emergency) during the course of the study. Subjects who receive dental treatment and/or use medication must report this to the study investigators. The use of tooth whitening products is prohibited. There will be no restrictions regarding diet during the course of the study. Subjects will be asked to return to the clinical facility 1 week post-treatment for subsequent clinical examinations.

Example of Label Instruction for both test and control groups (Appendix XI):

CRO-2025-09-WHT-MS

Product (Letter Code)

Brush your teeth twice daily (morning and evening) for two (2) minutes each time.
Cover the entire length of the bristled head with toothpaste. Do not swallow.
For investigational use only by the study participant. Not for Retail Sale.
For Adult Use Only. Keep out of reach of children under 6 years.
In case of emergency or for further information telephone:
Dr. John T. Gallob at 702-885-6984

Visits 2: (7 days +/- 3 days after Baseline):

1. Visit Form
   After 7 days of study product use at home, all subjects will report back to the clinical site for their follow-up appointment. The study examiner will complete a Study Visit Form (Appendix IX) to account for health updates and/or adverse reactions.

2. Subsequent Oral Soft and Hard Tissue Assessment

All subjects will return to the dental clinic, and receive an evaluation of their oral soft and hard tissues. The same examination and recording procedure employed at the previous visit will be repeated. The results of this evaluation will be recorded on the Oral Soft and Hard Tissue Assessment Form (Appendix VII). Any abnormal findings noted after the initial screening visit will be recorded as adverse events following the adverse event procedures listed below.

3. On-site brushing

Subjects will be asked to perform a supervised on-site brushing immediately prior to having the shade of their teeth graded.

4. Tooth Shade Assessment

The methods employed for tooth shade assessments will be repeated from the baseline appointment.

5. Extraoral Photos

In the subset of subjects, the methods employed for extraoral photos will be repeated from the baseline appointment.

6. Questionnaire

Subject and provider will complete the relevant portions of a short questionnaire.

Upon completion of the 7-day (final) visit, all subjects will discontinue product use and will return to their normal oral hygiene routine. An End of Study Visit Form (Appendix IX) will be completed for all subjects entered into the study even if they do not complete the entire 7-days duration of the study. Subjects will be interviewed with respect to adverse events and concomitant medications during the course of the study. All used and unused products should be returned to the clinical facility.

VI. DENTAL TREATMENT DURING THE STUDY

Subjects will be instructed to refrain from routine dental treatment (except emergency) during the course of the study. Subjects who receive dental treatment or use medication must report this to the study investigators.

Subjects will be interviewed with respect to adverse events and concomitant medications. A Visit/End of Study Form (Appendix IX) will be completed for all subjects entered into the study even if they do not complete the entire duration of the study.

VII. STATISTICAL METHODS AND DATA ASSESSMENT

Safety Analysis

Safety endpoints will include adverse events and oral examinations. Subjects who discontinue the study due to adverse events will be presented in a subject listing, as well as in a summary table. Adverse events for which a causal relationship to study medication could not be ruled out, will also be reviewed and discussed in a narrative format.

Data Analysis

The primary outcome variable of this study will be tooth shade whitening improvements via the Vita Extended BleachedGuide 3D-Master (29 tabs).

Demographics

A Chi-Square test will be performed on the gender demographic data to test the hypothesis that the Treatment groups are stratified and balanced with respect to gender. In addition, an analysis of variance (ANOVA) will be performed on the age demographic data to test the hypothesis that the mean age of the treatment groups are balanced with respect to age.

Outcome variables [Vita Extended Bleachedguide 3D-Master® (29 tabs)]

Shade changes between the baseline and each follow-up examination will be quantified by taking the difference in shade rank scores (where a positive difference is indicative of a lightening of the tooth, for example). Both the shade rank scores for each examination and the shifts in rank scores between examinations will be summarized for each subject by taking the mean across all measured teeth. Comparisons among the study treatment groups will be based upon an analysis of these mean scores.

Within Treatment Analysis

Within-treatment group comparisons between the baseline and post-treatment shade scores will be analyzed using a paired t-test. All statistical tests will be two-sided and employ a level of significance at the $\alpha = 0.05$.

Between Treatment Analysis

For the primary outcome variable, the shade change scores from baseline will be analyzed using an analysis of covariance (ANCOVA) model with treatment as a factor and the baseline shade scores as a covariate to compare the study treatment groups. Age and gender will be included as a covariate in the model, if they are determined to be statistically significant at baseline. P-values for the treatment group shade change comparisons, adjusted means

treatment group shade change differences and their 95% confidence intervals will be provided at all time points. All statistical test of hypotheses will be two-sided and employ a level of significance of $\alpha = 0.05$.

VIII. SUBJECT RECORD FORMS

The following subject record forms will be completed by the study investigators according to the following schedule:

Visit 1a (Screening/Baseline):

Informed Consent Form/Privacy Notice
Photo Release Form
Medical History/Oral Health Questionnaire
Initial Screening Form
Oral Soft and Hard Tissue Assessment Form
Tooth Color Assessment Form
Questionnaire

Visit 1b (Immediately after whitening)

Oral Soft and Hard Tissue Assessment Form
Tooth Color Assessment Form
Questionnaire

Visit 2: (7 days after baseline)

Visit/End of Study Form
Oral Soft and Hard Tissue Assessment Form
Tooth Color Assessment Form
Questionnaire

In addition, timely completion and report of adverse events (Appendix X) must be assured.

The investigator must make study data accessible to the sponsor's study monitor, to other authorized representatives of the sponsor, and to regulatory agency representatives. The original case report forms for each subject will be verified against source documents. A copy of the final case report forms will be placed in the investigator's study file, and the originals will be forwarded to the sponsor or its designee. Source data will be retained by the study site. The original source data will be maintained according to the Investigator's Standard Operating Procedures.

Source data comprise all the information contained in original records and certified copies of original records, including clinical findings, observations, laboratory reports, and data sheets provided by the sponsor, as well as other activities in the study that are necessary for the reconstruction and evaluation of the study. The investigator will allow study-related monitoring,

audits, IRB reviews, and regulatory inspections, providing direct access to all the required source records.

In this clinical trial, confirmation of screening, enrollment, randomization, study group assignment, log of product dispensing, medical history/oral health questionnaire and concomitant medications, data from oral soft tissue and hard tissue examinations, data from clinical assessments and visit forms to update subjects' health/medical condition post-enrollment will be captured on electronic case report forms (eCRFs). Direct data entry into eCRFs will be captured and stored in Colgate's Oral Care Clinical Veeva Vault. Paper case report forms (paper CRFs) will be used to capture all other data that will not be directly entered into the Veeva system, such as Informed Consent/Privacy Notice, study products inventory sheet and documentation of product use compliance. Paper CRFs will be retained as original source documents and will be scanned and uploaded to the Colgate Veeva Vault Clinical Suite.

Veeva Vault is a cloud-based Content Management System (CMS) developed by Veeva Systems. The Vault Clinical Suite includes Vault eTMF and Vault CTMS. Vault Clinical enables increased compliance of clinical processes, inspection readiness, and permits a unified and connected view of clinical operations business functions. In addition, Veeva Vault produces secure and compliant audit trails in accordance with the FDA 21 CFR Part 11 Electronic Records, Electronic Signatures, and Eudralex Annex11: Computerized Systems regulations. All data collected from the web based EDC hosted on a private Google Cloud Platform (GCP) cloud will be verified before being sent through encoded HTTP POST requests to the Veeva Vault cloud hosted on Amazon's Web Services cloud (AWS).

IX. RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

The responsibilities of the Principal Investigator are to ensure adherence to the protocol, complete the required forms, advise the monitor of any serious adverse reaction, and return any unused products to the sponsor of the study.

X. STUDY SITE AND EXAMINER

This study will be conducted under the direction of:

John Gallob, DMD

The study will be conducted at:

2717 N Wickham Rd Suite 1
Melbourne, FL 32935, USA

XI. SPONSOR'S AND INVESTIGATOR'S OBLIGATIONS CONFIDENTIALITY

Data

All information regarding the nature of the proposed investigation provided by the sponsor to the investigator (with the exception of information required by law or regulations to be disclosed to the IRB, the subject, or the appropriate national or local authorities) must be kept in confidence by the investigator, his/her staff or agents.

Subject Identity and Privacy

The anonymity of participating subjects must be maintained. Subjects will be identified by their assigned study identification number on all case report forms and other documents. Documents that identify the subject by name (e.g., the signed informed consent form and health questionnaire) will not be submitted to the sponsor, but must be maintained in strict confidence by the investigator, except to the extent necessary to allow auditing by the appropriate national or local authorities or to study sponsor personnel.

The Sponsor and the Investigator affirm and uphold the principles of respecting the subject's privacy. All records of subject participation are confidential and are available only to the Investigator, specifically trained site personnel, supervising dentist/examiner, potentially the study Sponsor, governing ethics committees and competent local regulatory agencies upon request or as required by applicable law. In addition, the identity of participating subjects must be protected. Accordingly, only investigators (and specifically trained clinical site staff) will collect and have access to a subject's private information (e.g., name, medical records, etc.). Investigators will assign a study number to subjects which will be used to conceal their identity on all case report forms and other documents prior to their sharing with the broader study team, including the Sponsor. Documents that identify the subject by name (e.g., the signed informed consent form or health questionnaire) will not be transferred or submitted to the Sponsor and will be maintained in strict confidence by the Investigator, except to the extent necessary to allow auditing by the competent authorities or to trained Sponsor personnel only as necessary to verify subject, product safety and study compliance, or as otherwise required by applicable law. The results of the study may be published in a scientific journal or a government public clinical database. If any publication occurs, only the subject's study number/ID, gender and/or age may be included in the publication used.

The Investigator/Investigator's designee will provide each subject with a Privacy Form regarding the processing in connection with the study of personal data (i.e., any information relating to an identified or identifiable individual) by the Investigator, the Sponsor and other persons involved in the study. Each subject will be given a copy of the Privacy Form, and the Privacy Form will be referenced in and form a part of the overall study informed consent/notice process.

A Privacy Form is included in this Protocol that must be provided to each subject. Any deviation to the Privacy Form in regards to processing by the Sponsor (including its vendors, Monitors and other representatives) prior to the approval of this Protocol, or change to the Privacy Form after the signing of this Protocol, will be handled in accordance with section 14 of this Protocol. The Investigator is responsible for ensuring the Privacy Form includes any local requirements regarding data security and privacy laws and regulations applicable to the study and the subjects. Should the

Privacy Form fail to meet any applicable local requirements, the Investigator is responsible for amending the Privacy Form to bring it into compliance with local applicable regulations and the Investigator (including Principal and sub-Investigators) agrees to indemnify and be liable to the Sponsor for any damages resulting from such non-compliance.

Confidentiality

All records of your participation in this study are confidential and these records are available only to the Investigator, Supervising dentist, sponsoring company, Ethics or Institutional Review Board (IRB), and possibly the Food and Drug Administration of the United States. The results of this study may be published in a scientific journal or a government public clinical database. If any publication occurs, only the subject's study number/ID, gender and/or age may be used. They will agree to verify, by letter, that they participated in this study, if called upon to do so.

XII. PROTOCOL APPROVAL, STUDY MONITORING, AND COMPLIANCE

Institutional Review Board

The clinical investigation, including the consent form, will be reviewed by an Institutional Review Board in accordance with Title 21 of the Code of Federal Regulations, Parts 50 and 56. Approval by the Board must be obtained prior to the initiation of the study.

The study will be conducted in compliance with Good Clinical Practice Regulations, the study protocol, and protocol amendment(s). Designated personnel will audit this study to ensure protocol compliance. In addition, study data and the Final Report will be examined for completeness, accuracy, and proper documentation.

Informed Consent and Other Written Information for Subjects

The informed consent form and any other written information for subjects should meet local requirements of language and interpretation (i.e., non-English speaking subjects must be presented with informed consent forms in a language that they can understand). One copy of the signed informed consent form and any other written information will be given to the subject, parent, or legal representative, and the original will be retained by the investigator in the study files. The informed consent form and any other written information prepared by the investigator must be reviewed and approved by the sponsor and by the Institutional Review Board prior to their implementation. The informed consent form must include all required elements in accordance with GCP guidelines. A sample informed consent for this study is provided in Appendix II.

Protocol Compliance

The investigator is obligated to follow the provisions and requirements of the study protocol accordingly. Any changes to the protocol must be implemented only through formal written protocol amendments and only upon joint approval by the sponsor and investigator. All protocol amendments must be reviewed and approved prior to implementation by the institutional review board (IRB), U.S. Investigational Review Board, Inc. (**U.S. IRB, Inc.®**) 8050 SW 72 Avenue, #2105, Miami, Florida 33143; Telephone: 1-786-473-3095. If a protocol amendment requires changes to the informed consent form, the revised consent form must also be approved by the sponsor and the IRB.

Departures from eligibility requirements may be allowed on a case-by-case basis by the medical monitor or other authorized sponsor representative. Such departures must be medically and scientifically justified, must be pre-authorized, and must be documented in the case report form and tracked as official eligibility waivers.

Investigational Drug Accountability

It is the responsibility of the investigator to ensure that proper procedures are implemented with regard to the receipt, storage, and dispensation of the test products. Shipping receipts, dispensing records, and inventory form(s) located at the site will be examined and reconciled periodically and at the end of the study by the study monitor. All the test products used during the course of the study and any remaining unused test product must be accounted for on the accountability log provided to the investigator by the sponsor.

Study Monitoring

The study will be monitored by members of the Oral Care Clinical Research Department of Colgate-Palmolive at periodic intervals during the course of the study to ensure that the study is being conducted according to Good Clinical Practice Guidelines.

General Procedures

The sponsor's study monitor will review the progress of the study as frequently as is necessary to ensure adequate and accurate data collection. Monitoring activities may include:

- Periodic on-site visits
- Telephone communications with the site
- Ongoing review of case report forms, clinical records, and administrative documents

All records pertaining to the study will be made available to the study monitor during each site visit. Routine monitoring visits will be planned and confirmed in advance, as much as possible, to allow adequate time to assemble these records. Unplanned visits may occur as dictated by study necessities.

Important agreements and discussions between the sponsor and investigator should be documented for the study file. Examples include: eligibility criteria exceptions, agreements to deviate from protocol-defined procedures, notifications of subject withdrawal, etc.

Reports

The final report for the sponsor will summarize the method, statistical analyses, data and conclusion relative to the test product, the subject completing the study, and summarize any adverse events and deviations. Source data will be retained by the study site. Copies of the transcribed data will be incorporated in the final report as data tables.

Record Retention and Access to Source Data/Documents

Source documents must be kept for at least five (5) years after terminating the study. The Investigator will maintain all study documentation for all subjects entered into the study in a secure area ensuring the confidentiality of the information collected. Securing records includes placing written forms in locked file cabinets and/or sealed and labeled storage boxes in a locked room. Access will be denied to all persons with the exception of the Principal Investigator and his/her designees. In the event that clinical records cannot be securely kept by the clinical site for the agreed to time, the study sponsor will be notified before the destruction of any study records occurs. The study sponsor maintains the right to keep the clinical records for the agreed time limit.

XIII. STUDY PRODUCT MANAGEMENT

Study Products

Study products will be supplied by the sponsor for this study. The study investigator will verify that the quantity of supplies, protocol number, and identification numbers match the information on the shipping invoice, and will store and account for the study supplies as described below.

Study Products Storage, Handling, and Accountability

The study products must be stored in a secure area with limited access, at room temperature. The investigator is directly responsible for the accountability of all used and unused study products. The investigator and all sub-investigators will make every effort to remain blinded as to the subject regimen. Records must be maintained to document the receipt and disposition of all study drug supplies provided to the investigator by the sponsor. The study monitor will review these records periodically during the course of the study. At the end of the study, or as directed by the monitor, the investigator must return all unused study products to the sponsor.

XIV. CONCOMITANT THERAPY

If a subject takes concomitant medications as a matter of necessity for the treatment of a medical condition, then such medication may be permitted for the duration of the study at the discretion of the investigator. However, it is the responsibility of the investigator to disqualify from entering the study any subject who, upon screening, is using medication or consumer products that might obscure the interpretation of study results. All medications currently used by the subject at enrollment, or any time through the end of the study, will be recorded on medical history and visit form. Subjects may receive medication to treat adverse events as deemed necessary by the investigator or the subject's physician.

XV. ADVERSE EVENTS

A. DEFINITIONS:

Adverse Events (AEs) and Serious Adverse Events (SAEs) are defined by the ICH Guideline for Good Clinical Practice (ICH GCP) as follows:

Adverse Event: Any untoward medical occurrence in a patient or clinical investigations subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

AEs include any clinically significant deterioration of a subject's medical status, after being enrolled in the study and signing an Informed Consent form. The AE may involve any organs or systems and can be represented by the new onset or the deterioration of a disease, a syndrome, a symptom, a physical sign, as well as by findings and results of instrumental examinations and laboratory tests. Any medically relevant and untoward change from baseline, including frequency or pattern changes for a fluctuating condition (e.g., migraine), occurring after the first administration of study medication is an adverse event. All such occurrences must be recorded and reported accordingly, whether they appear causally related to the study medication, or not.

Serious Adverse Event: Any adverse event occurring at any dose that results in any of the following outcomes:

- Death
- Life threatening adverse event
- Inpatient hospitalization, or prolongation of existing hospitalization
- Persistent or significant disability/incapacity
- Congenital anomaly/birth defect

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

Examples of such important medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

B. IMPORTANT NOTES:

The concepts of Adverse Event / Experience (AE) and Serious Adverse Event / Experience (SAE) represent **regulatory** instruments used to evaluate and monitor the safety of clinical trial subjects. Therefore, these terms only apply in light of their regulatory definition. The term "serious", in a regulatory sense, does not necessarily mean "severe". All adverse events (serious and non-serious) reported during a study will be taken into account when analyzing the study data and establishing the safety profile of the investigational drug, and will be included in the final study report. The SAE concept is primarily used to identify, during the conduct of the trial, those adverse events that may require an expedited reporting procedure to regulatory authorities.

Death: The outcome of death requires that the AE that resulted in death be reported as an SAE. Death, in and of itself, is not an AE; it is only an outcome. The cause of death is the AE; therefore,

the investigator should make every effort to obtain and document the cause of death for all subjects who die during the study. If, despite all efforts, the cause of death remains unknown, the AE should be documented as "unspecified fatal event".

Life-threatening Adverse Event: Any adverse event that places the patient or subject, in the view of the investigator, at immediate risk of death from the reaction as it occurred (*i.e.*, it does not include a reaction that had it occurred in a more severe form, might have caused death).

Hospitalization: It should be noted that hospitalization, in and of itself, does not represent an SAE. It is the adverse event leading to the subject's hospitalization that becomes "serious" when it requires inpatient care. Consequently, SAE should not be reported in case of pre-planned hospitalizations for pre-existing conditions that did not worsen during the study.

Disability: A substantial disruption of a person's ability to conduct normal life functions.

C. REPORT AND DOCUMENTATION OF ADVERSE EVENTS:

All adverse events forms are provided in Appendix X (Forms 105361 and 105362).

General Procedures for All Adverse Events

All clinical complaints, symptoms, or signs that meet the adverse event definition will be recorded on the Non Serious Adverse Events case report form (CRF) using a recognized medical term or diagnosis that accurately reflects the event. Source documentation should be maintained that allows for clear identification of each adverse event and the following parameters required for the CRF:

- AE description
- Date of onset
- Date of resolution
- Outcome
- Severity
- Seriousness
- Relationship to study drug (causality)
- Actions taken

Adverse events will be assessed by the investigator or designee for severity, relationship to the study product, possible etiologies, and whether the event meets the criteria as a serious adverse event and therefore requires immediate notification of the sponsor.

For CRF data collection purposes, the outcome of all adverse events recorded on the Adverse Event form should be reported within two (2) weeks of the study completion. The investigator will include this information in the Site Report providing a line listing using the Periodic/End of Study Report Form and attaching the individual adverse event form for each case reported. However, the investigator is responsible for following all adverse events until resolution or until no longer of clinical concern, and providing these data to the sponsor.

When protocol duration is six (6) months or longer, a Periodic/End of Study Report Form must be completed and included as part of your Site Report every six (6) months for the duration of the protocol.

Reporting Procedures for Serious Adverse Events

Any adverse event that is serious or potentially serious requires additional detailed reports and follow-up. A serious adverse event must be reported to the sponsor's representative immediately (within 24 hours). A Serious Adverse Event Report Forms must be completed so as to facilitate discussion and implementation of necessary follow-up measures, and to enable the sponsor to submit necessary reports to regulatory authorities and other investigators. Once the sponsor reviews the Serious Adverse Event Report Form, additional information may be requested from the investigator to allow appropriate medical evaluation and determine the regulatory reporting requirements.

The investigator is responsible for following all adverse events, especially those deemed "serious", until resolution or until the event is no longer of clinical concern, and for providing all data to the sponsor in an agreed-upon format. The investigator is also responsible for reporting all serious adverse events to the Institutional Review Board (IRB) overseeing the conduct of the study at the respective study center, according to the rules and procedures established by this committee.

SAE/SAR Reporting

Study Originator (SO) receives Form 105361 Adverse Event/Reaction Reporting Form for Non-interventional Studies from the investigator and forwards to globalpcb@colpal.com and scrp@colpal.com within one (1) calendar day (no later than 1 business day) of receipt.

Non-Serious AER Reporting

Study Originator (SO) receives the Form 105361 Adverse Event/Reaction Reporting Form for Non-Interventional Studies from the investigator for non-serious AER within one (1) calendar day (no later than 1 business day) of investigator awareness and forwards to globalpcv@colpal.com and scrp@colpal.com within one (1) calendar day (no later than 1 business day) upon receipt from investigator.

End of Study Reporting

Within 2 weeks of study completion the SO must complete Form 105362 Periodic/End of Study Report Form for Non-Interventional Studies on Humans documenting adverse event/reaction information reported during conduct of the study and submits it to globalpcv@colpal.com and scrp@colpal.com.

XVI. PREGNANCY

No self-reported pregnant women will be enrolled in this study. In the event a woman enrolled in this clinical research study becomes pregnant during the course of the study, participation in this study will be terminated upon the clinical staff's notification of the event. The subject's medical records used in this study will be updated to reflect the pregnancy and there will be follow- up contact until the end of the pregnancy to record the outcome in the clinical file.

XVII. SUBJECT TERMINATION/WITHDRAWAL PROCEDURES

A genuine effort will be made to determine the reason(s) why a subject fails to return for the necessary visit(s) or is dropped from the study. Subjects could be dropped from the study if any of the following occur:

1. Subject fails to substantially comply with the protocol requirements.
2. Subject fails to report for a scheduled examination.
3. Subject is treated with medication(s) during the course of the study, which may interfere with the parameters under study.
4. Subject receives emergency dental or medical treatment, which may interfere with the parameters under study.
5. Subject develops a serious adverse reaction. The Study Investigator will immediately notify the study monitor and information will be recorded on an Adverse Reaction Form (Appendix X).
6. Sponsor elects to terminate the study.
7. Subject elects to terminate participation in the study.

A study Visit Form (Appendix IX) indicating end of study participation must be completed for all subjects entered into the study even if they do not complete the study.

XVIII. NEW FINDINGS

Subjects will be informed of any significant new findings related to study products or procedures when they become known during the course of this clinical research study. Such information may affect the subject's decision to continue participation in the study.

APPENDIX I
Tooth Shade Assessment Guidelines

Room and Lighting Conditions

- Assessments are conducted in a windowless room with the door closed to control ambient light.
- Only color-corrected overhead lighting between 5500-6500 Kelvin is used, simulating natural daylight. No operatory lights are used.

Subject Preparation

- On-site, supervised brushing with assigned product prior to clinical examinations.
- Subjects wear a blue or gray bib to neutralize clothing color influence.
- All makeup, hats, jewelry, and accessories are removed to avoid interference with shade selection.

Positioning

- Chair height and subject position are adjusted to provide a direct, shadow-free view of maxillary anterior teeth.
- All examinations are performed with the subject in the same position for consistency.
- Subjects are instructed to smile without showing their tongue.

Assessment Procedure

- A single, trained, and calibrated examiner (dentist) conducts all assessments.
- The examiner focuses on the facial (middle third) area of the tooth.
- The shade matching tab is held adjacent to the subject's tooth during assessment for comparison.

Visual Fatigue Management

- The examiner waits at least 5 minutes between assessments, resting their eyes on a blue background to prevent visual fatigue, for consistent and reliable tooth shade assessments.

APPENDIX II

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

Subject's Initials _____ Date _____

Title: Clinical Study to Evaluate the Tooth Whitening Efficacy of a new NextGen in-office whitening system

Sponsor: Colgate Palmolive Company

Examiner(s): John Gallob, DMD

Clinical Site: 2717 N Wickham Rd Suite 1 Melbourne, FL 32935, USA

INVESTIGATORS STATEMENT

You are being asked to volunteer for a dental research study. Before agreeing to participate in this research study, it is important that you read this form. This form, called a consent form, describes the purpose, procedures, benefits, financial payment, risks, and discomforts of this research study. It also describes the alternative procedures that are available to you and your right to withdraw from this research study at any time. No promises or guarantees can be made as to the results of this research study. Please ask as many questions as you want in order to decide whether you want to be in this research study. This consent form may contain words that you do not understand. Please ask the research study doctor or the research study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or to discuss with family or friends before making your decision.

PURPOSE OF THIS RESEARCH STUDY

The objective of this clinical research study is to evaluate the Clinical efficacy of a NextGen in-office whitening system compared to commercially available in-office whitening systems.

STUDY POPULATION

You are being considered for participation in a one (1) week clinical research study to be conducted by Dr. John Gallob (Investigator) and sponsored by the Colgate-Palmolive Company (Sponsoring Company). Approximately one hundred and eighty (180) healthy adults like yourself will be enrolled for voluntary participation in this study. The research study participation will consist of a total of two (2) visits to the clinical site over the one (1) week study period.

APPENDIX II

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

U.S.IRB

Subject's Initials _____ Date _____

IRB #: U.S.IRB2025CP/14
VERSION: OCTOBER 7, 2025
VALID TO: OCTOBER 6, 2026

OCT - 7 2025

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SPECIFIC PROCEDURES TO BE USED

In order to be selected for participation, you must meet certain inclusion criteria:

1. You must provide consent to participate by signing this informed consent form.
2. You must be at least eighteen (18) years old and not older than seventy (70) years of age.
3. You must be in good general health and good oral health based on the opinion of the research study examiner.
4. You must have all your top front teeth present.
5. You must be available for the duration of the research study.
6. Your top front teeth must meet a minimal tooth shade at the discretion of the study examiner.

In addition, you must not have / must not be:

1. Orthodontic appliances or any top front tooth with a crown or veneer.
2. Obvious signs of periodontal disease (gum disease), or any other condition that the dental examiner considers would exclude you from participation.
3. Five (5) or more cavities requiring immediate care.
4. Participation in another oral care clinical study.
5. Self-reported pregnant or lactating women.
6. History of allergies to tooth whitening products, hydrogen peroxide, personal care consumer products, or their ingredients.
7. Restorations on the teeth to be scored which may interfere with scoring procedures.
8. Have used a professional whitening product within one (1) year and/or had a professional cleaning within thirty (30) days prior to the start of the research study.

Visit 1 (Screening/baseline)

The research study examiner will perform a screening and initial examination to determine whether you qualify to enter this research study, and will:

- Collect your demographic information (age, date of birth, initials, gender, etc.).
- Have you completed a medical questionnaire and been interviewed about your medical and dental history
- Examine tissues in your mouth to check for abnormalities, *e.g.* evidence of gum disease, irritations, lacerations, or ulcerations.
- Assess the color of your six (6) front teeth using a tooth bleaching guide.
- Randomly assign you (by chance, like flipping a coin) to use one (1) of four (4) tooth whitening treatments for in-office application.

APPENDIX II
RESEARCH SUBJECT INFORMATION AND CONSENT FORM

U.S.IRB

Subject's Initials _____ Date _____

IRB #: U.S.IRB2025CP/14
VERSION: OCTOBER 7, 2025
VALID TO: OCTOBER 6, 2026

OCT - 7 2025

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- Take photos of your teeth.
- Issue your assigned study products for the remaining 1-week research study period.
- Verbally instruct you about this research study's treatment requirements.
- Perform a professional in-office whitening treatment.
- You will be instructed to thoroughly brush your teeth two (2) times daily (morning and evening) for two (2) minutes at each brushing using the toothpaste that will be provided to you. You will then be asked to continue the use of this product for the duration of the study.
- Remind you not to use oral care products (e.g. toothbrushes, toothpaste, dental floss, mouthwashes, chewing gum, breath films or strips, or other oral care cleaning aids) other than those you have been assigned for the duration of this research study.
- Confirm your follow-up appointments.

The research study dental examiner will not know which product you are assigned to use. However, this information is available to the research study dentist in an emergency. The instructor will advise you not to discuss your product with the examiner or other subjects for the duration of this research study.

You will need to bring all remaining assigned products at each visit.

Visits 2 (1 week of Product Use)

After 1 week of product use at home you will return to the clinic. During these research study visits the principal investigator/staff will:

- Update your medical/dental history for any changes in your health or new medicines since previous study visit.
- Interview you to determine if you were able to follow the instructions and use the assigned test products correctly during the treatment phase of this research study.
- Ask if you encountered any problems during this research study, and record any comments.
- Perform a supervised on-site brushing with the study products assigned to you.
- Assess the color of your six (6) front teeth using a tooth bleaching guide.
- Again take photos of your teeth.
- Examine the tissues inside your mouth to check for abnormalities.
- You will receive a payment for your participation and will be dismissed from this research study.

APPENDIX II
RESEARCH SUBJECT INFORMATION AND CONSENT FORM
PAGE FOUR OF EIGHT

Subject's Initials _____ Date _____

IRB #: U.S.IRB2025CP/14
VERSION: OCTOBER 7, 2025
VALID TO: OCTOBER 6, 2026

SUBJECT RESPONSIBILITIES

You must be available to attend each research study visit.

During this research study, you will not be allowed to use any other non-assigned dental products (including toothpastes, floss or other products like chewing gum, mouthwashes, tongue cleaners, etc.) or have your teeth cleaned or whitened at a dental office. You must use only the test products given to you during this entire research study. You may continue using dental floss if it is already part of your normal oral care regimen.

LENGTH OF PARTICIPATION

The research study participation will consist of a total of two (2) visits to the clinical site over the one (1) week study period. All exams will take place at the dental clinic. If you qualify and you are enrolled after the screening exam, you will only use your research study products provided by the study staff for the duration of this study. Approximately one hundred and eighty (180) subjects will complete this research study.

RISKS TO THE SUBJECT

The risk of permanent harm, injury, or disability as a result of participation in this research study is minimal. The dental exams are similar to those used as part of routine oral health care. Your participation is not expected to cause any oral conditions different from those normally experienced in routine dental care. No known side effects or risks are associated with the use of the study products. Temporary tooth sensitivity and oral soft tissue irritation have been reported with the use of whitening products. The reactions are not harmful and resolve once the whitening treatment is withdrawn.

Precautions:

- All products given to you as part of this research study are for your use only.
- Keep all assigned products out of the reach of children and persons who may not be able to read or understand the label, as well as pets.

APPENDIX II
RESEARCH SUBJECT INFORMATION AND CONSENT FORM
PAGE FIVE OF EIGHT

U.S.IRB

Subject's Initials _____ Date _____

IRB #: U.S.IRB2025CP/14
VERSION: OCTOBER 7, 2025
VALID TO: OCTOBER 6, 2026

OCT - 7 2025

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If you experience any problems or any research related injury, you are to contact the Study Investigator Dr. John T. Gallob at their 24-hour emergency number 702-885-6984. If you were unable to contact him please call your physician, or the Poison Control Center at 1-888-489-3861. You understand that if any physical injury results from your use of the test products, the Sponsoring Company will be responsible for medical costs provided if you seek medical attention as directed by the sponsoring company or as directed by the research study investigators.

BENEFITS TO THE SUBJECT

Participation in this research study may not benefit you personally. The results of the research study may help to find alternative methods of whitening your teeth. There are other therapeutic treatments that could help with tooth whitening, such as, toothpastes, mouth rinses and professionally administered procedures.

COSTS

You will not be charged to participate in this research study.

PAYMENT FOR PARTICIPATION

You will be compensated for your participation in this study. For each study visit completed you will receive a per diem of $ 40.^{00}$ to cover food and transportation costs plus a $ 30.^{00}$ bonus at the end of the study for your time and compliance. You must meet all attendance requirements and return all the test products at the end of the study. If you do not complete the study of your own free will, you may receive a pro-rated portion of the compensation at the discretion of the Study Investigators.

ALTERNATIVE TO PARTICIPATION

Your alternative is not to participate in this research study. If you decide not to participate in this research study you may use one of the many over-the-counter tooth whitening treatments that you can purchase to achieve your desired whitening effect. You may also see a dentist for professional whitening treatment.

VOLUNTARY PARTICIPATION / WITHDRAWAL

You are under no obligation whatsoever to participate in this study and your participation in this study is strictly voluntary. You may withdraw or discontinue participation at any time, without penalty or loss of benefits to which you would otherwise be entitled. You may also withdraw your consent for the use of your data, but you understand that you must do this in writing. You understand that the investigator has the right to withdraw you from the study at any time. Any data that has already been sent to Colgate Palmolive Company cannot be withdrawn because there may not be any identifiers with the data.

APPENDIX II
RESEARCH SUBJECT INFORMATION AND CONSENT FORM

U.S.IRB

Subject's Initials _____ Date _____

IRB #: U.S.IRB2025CP/14
VERSION: OCTOBER 7, 2025
VALID TO: OCTOBER 6, 2026

OCT - 7 2025

"APPROVED"

At any time, the research study monitor/investigator can take you out of this research study because it would not be in your best interest to stay in it. Your study doctor can stop treatment even if you are willing to stay in the study.

In the event a woman enrolled in this clinical research study becomes pregnant during the course of the research study, participation in this research study will be terminated upon the clinical staff's notification of the event. Your medical records used in this study will be updated to reflect the pregnancy and you will have follow-up contact until the end of the pregnancy to record the outcome in your file.

If you decide to pull out of the research study for any reason, you may be asked to return for at least one additional visit for safety reasons.

CONFIDENTIALITY
The results of this research study may be published in a scientific journal and/or public clinical trials government website. Your identity will be kept confidential, only your subject number/ID or initials, gender and/or age may be used to identify you in any such publication of the study results. You understand that the study records and any medical records obtained as a result of your participation in the study will be examined by the Investigator, Sponsor (Colgate-Palmolive Company) and may also be examined by an institutional review board (IRB), regulatory agencies or the FDA.

MAINTENANCE AND CONFIDENTIALITY OF DENTAL/MEDICAL RECORDS
Your dental/medical records will be kept in accordance with state and federal laws concerning the privacy and confidentiality of medical information. If your participation in this research is for treatment or diagnostic purposes, the facility in which you are treated may ask you to sign a separate informed consent document for specific procedures or treatment, and that informed consent form may be included in the dental/medical record of that facility. The confidentiality of your dental/medical record is also protected by federal privacy regulations.

Subjects' study charts will be stored in a secure locked room designated for research charts storage in the clinical site. The chart room is a limited-access area, and only delegated study personnel will have access to the study charts and subjects' data.

NEW FINDINGS
You will be informed of any significant new findings related to research study products or procedures as soon as they are known. Such information may affect your decision to continue participation in the research study.

APPENDIX II

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

PAGE SEVEN OF EIGHT

U.S.IRB

Subject's Initials _____ Date _____

IRB #: U.S.IRB2025CP/14
VERSION: OCTOBER 7, 2025
VALID TO: OCTOBER 6, 2026

OCT - 7 2025

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Right to Leave the Study

Your participation is voluntary and you may withdraw from this study at any time without prejudice.

QUESTIONS

If you have any questions about this research study, or if you feel you have experienced a possible side effect, reaction to this research study product, or a research-related injury, contact the study investigators:

Dr. John T. Gallob, DMD
President/Owner Consumer Research Consulting, LLC
5311 Strankman Ave
Las Vegas, NV 89131
Telephone: 702-885-6984
Email: John.gallob@crc-florida.com

If there are concerns about your rights as a research subject, you may contact:

Rosa M. Fraga, Chairperson
U.S. Investigational Review Board, Inc. (U.S. IRB, Inc. ®)
8050 SW 72 Avenue, #2105
Miami, Florida 33143
Telephone: 1-786-473-3095
E-mail: rmvf1550@aol.com

U.S. IRB, Inc. ® is a group of people who perform independent review of research for protecting the rights and safety of research participants.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions. If you agree to participate in this research study, you will be given a signed and dated copy of this consent form to keep.

APPENDIX II

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

PAGE EIGHT OF EIGHT

U.S.IRB

OCT - 7 2025

"APPROVED"

_____ _____

Subject's Initials Date

IRB #: U.S.IRB2025CP/14
VERSION: OCTOBER 7, 2025
VALID TO: OCTOBER 6, 2026

CONSENT

Your signature below signifies that you understand and agree to the above and affirms that you have volunteered to participate of your own free will. Further, you assert that you are eighteen (18) years of age or older but not older than seventy (70) years of age and not nursing a baby or pregnant and that you were given the opportunity to ask questions about the research study.

I have read the information in this consent form. All my questions about this research study and my participation in it have been answered. I freely consent to participate in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not waived any of my legal rights which I otherwise would have as a subject in a research study.

_____ _____

Subject's Signature Date

_____

Subject's Name (Please print)

_____

Person Conducting Informed Consent Discussion Name (Please print)

_____ _____

Signature of Person Conducting Informed Consent Discussion Date

For further information regarding your rights as a volunteer, contact Rosa M. Fraga, Chairperson of the U.S. Investigational Review Board, Inc. ® (U.S.IRB, Inc. ®) at 1-786-473-3095 or rmvf1550@aol.com.

APPENDIX III
PRIVACY NOTICE
PAGE ONE OF THREE

This Privacy Form describes how information relating to you (i.e., personal data) is collected and used in relation to the study for which you completed an Informed Consent Form, and describes your privacy rights in respect of your participation. Please take a moment to familiarize yourself with it and complete it as appropriate.

What personal data about you will be collected?

If you join the study, your dentist, physician, health practitioner or other relevant investigator, and authorized persons ("**Study Team**") will collect personal data about you in connection with the study, which may include administrative information (e.g., name, address and emergency contact details), demographics (e.g., date of birth, age, language and gender), personal situation and lifestyle (e.g., consumption habits), body metrics (e.g., weight and height), samples, images and test results, study-related events and documentation, ethnicity and medical history and condition. The personal data will be collected directly from you, for example during exams, or as part of your medical history, and from your usual health practitioner. Some personal data may also be collected from publicly available databases, for example to re-establish contact with you in case of a safety issue. Note that the provision and use of personal data under the study is required for you to participate in the study and that, absent such provision, you may not be able to participate in the study.

How will your personal data be used?

Your personal data may be used by the Study Team and the sponsor [described in the Informed Consent Form as relevant/●] for the purposes set out below. As set out further below, to safeguard your privacy, the sponsor only receives and uses personal data in a coded form, except for specific cases and individuals who may access non-coded personal data such as study auditors and monitors.

- **To perform the study research** as described in the Informed Consent Form (including assess the effects of relevant products, publish study results and product commercialization), and for further research, to [●]. The Study Team and the sponsor perform the above activities with your consent as set out at the end of this Privacy Form.

- **To comply with legal duties** including reliability and safety requirements, such as audit and monitor the study and adverse events, perform [stability analysis], report to and communicate with competent authorities such as regulatory and inspections authorities and ethics committees that review the study to verify that it meets safety, reliability and ethical standards ("**Competent Authorities**") , and [●].The Study Team and sponsor perform the above activities to comply with legal obligations and public interest in the area of health.

Who will have access to your personal data?

Your personal data may only be disclosed by the Study Team to limited persons, in particular:

- Competent Authorities.
- Your usual health practitioner in connection with the study.
- Specific persons in charge of auditing or monitoring the reliability, safety and compliance of the study, which may include persons employed by the sponsor.

APPENDIX III
PRIVACY NOTICE
PAGE TWO OF THREE

- Persons supporting the Study Team and duly authorized to access the personal data, such as clinical research organizations or data managers, or those [ensuring liability for the study].

How is your privacy protected?

To safeguard your privacy and ethical standards, **your personal data will be coded** by the Study Team. This means that a unique code will be used in place of other data that could directly identify you, such as a name or contact detail. The Study Team will keep the link between the code and such identifiers confidential. In addition, your personal data in a coded form may only be disclosed to limited persons (aside from those persons identified above), in particular to:

- The sponsor, and its relevant affiliates and service providers supporting in the study (such as those providing data analysis and hosting, quality control, information technology and related infrastructure provision, customer and pharmacovigilance services, advisors, auditing, laboratories and shippers/couriers where appropriate).
- Mandatory public disclosure platforms, such as the publication of age and gender on global clinical websites.
- Other researchers, peer reviewers and relevant study-related experts, such as compliance counsels and heads of research.

How will your personal data be protected when transferred outside the EU/EEA?

Your personal data may be transferred to countries around the world in connection with the study. Some countries may have data protection laws that are different from those in the country in which you are participating in the study. As regards personal data from the European Economic Area ("**EEA**", i.e., the European Union's Member States plus Iceland, Liechtenstein and Norway), some non-EEA countries are recognized by the European Commission as providing an adequate level of data protection according to EEA standards (a list of which is available at https://ec.europa.eu/info/law/law-topic/data-protection/data-transfers-outside-eu/adequacy-protection-personal-data-non-eu-countries_en). For transfers from the EEA to other countries, including the U.S., adequate measures are sought to protect your personal data, such as identifying reasons of public interest or contracting measures, such as standard contractual clauses adopted by the European Commission and similar data transfer agreements. To know more about or obtain a copy of these measures where appropriate, please contact your Study Team.

How long will your personal data be stored?

Your personal data will be kept for as long as needed or permitted in light of the purposes for which they were obtained and consistent with applicable law. The criteria used to determine such retention periods include:

- Whether there is a legal or regulatory obligation to retain the personal data (for example, certain laws require to archive study data for several years after the end of a study).
- Whether retention is advisable in light of the data holder's legal position (such as in regard to applicable statutes of limitations, litigation or regulatory demands).
- Technical and operational standards, such as ensuring system and data integrity, continuity availability and resilience, including preventing study or data biases or corruption.

APPENDIX III
PRIVACY NOTICE
PAGE THREE OF THREE

What privacy rights do you have?

You have the right to request to review, correct, delete, restrict, object to the use or receive a portable copy of your personal data. Note that such rights may be suspended or restricted under the study, or that exercising them may affect your participation in the study. For example, some studies may be blinded, in that you may not be supposed to know whether you are receiving actual medication or a placebo or know the details of the sponsor until the study is completed. If you choose to exercise your privacy rights such as the right of access to your personal data or details of the sponsor despite the blinding, you may not be able to continue participating in such study.

Similarly, there may be legal or regulatory requirements to retain data that have been collected as a part of a study, despite your right to request their deletion. If personal data in a coded form have been used or included in a publication, it may not be possible to delete them.

You have the right to withdraw at any time your consent to the use of your personal data where you provided it. Should you choose to withdraw your consent, your Study Team may ask you to undergo an end of study examination and thereafter stop collecting your personal data as part of this study. If you withdraw your consent for the use of your personal data, you will not be able to continue taking part in the study. Personal data that were already collected prior to your withdrawal may be retained to the extent they relate to legal duties for example, such as reliability and safety requirements. Contact information which you provided may for example be used to re-establish contact with you if necessary for safety reasons, reporting duties or a vital interest, such as a life status check. Publicly available information such as public registers or social media may also be used for these purposes.

To submit a request concerning your personal data, please contact your Study Team. For more information about your privacy rights, or if you are not able to resolve a problem directly with the Study Team and wish to make a complaint, you can contact a data protection authority competent for your country (a list of which is available at https://edpb.europa.eu/about-edpb/board/members_en).

Please check as appropriate:
☐ I consent to my personal data being collected and used for the study research as described above.
[**Optional**: ☐ I consent to the further use of my personal data as described above.]

Participant Name: _____

Date: _____

Signature: _____

APPENDIX IV
THE Colgate Palmolive PHOTO RELEASE FORM

I hereby grant Colgate Palmolive permission to use my likeness in a photograph, video, or other digital media ("photo") in any and all of its publications, including web-based publications, without payment or other consideration.

I understand and agree that all photos will become the property of Colgate Palmolive and will not be returned.

I hereby irrevocably authorize Colgate Palmolive to edit, alter, copy, exhibit, publish, or distribute these photos for any lawful purpose. In addition, I waive any right to inspect or approve the finished product wherein my likeness appears. Additionally, I waive any right to royalties or other compensation arising or related to the use of the photo.

I hereby hold harmless, release, and forever discharge Colgate Palmolive from all claims, demands, and causes of action which I, my heirs, representatives, executors, administrators, or any other persons acting on my behalf or on behalf of my estate have or may have by reason of this authorization.

I HAVE READ AND UNDERSTAND THE ABOVE PHOTO RELEASE. I AFFIRM THAT I AM AT LEAST 18 YEARS OF AGE, OR, IF I AM UNDER 18 YEARS OF AGE, I HAVE OBTAINED THE REQUIRED CONSENT OF MY PARENTS/GUARDIANS AS EVIDENCED BY THEIR SIGNATURES BELOW. I ACCEPT:

_____
Print Name

_____ _____
Signature Date

APPENDIX V

SAMPLE OF HEALTH QUESTIONNAIRE

Name: _____ today's date: _____

Date of Birth: _____ Race: _____ Smoker: [ ] Yes [ ] No

MEDICAL HISTORY

Name of Physician: _____ Phone#: _____

Date of last visit: _____ Emergency contact? Name: _____

Phone #: _____Your current physical health is: ___ Good ____Fair ____Poor

Have you ever had any serious operations? [ ] Yes [ ] No

If yes, please explain: _____

Are you currently under the care of a physician? [ ] Yes [ ] No

If yes, Please explain: _____

Please check if you have been treated for or told that you have:

[ ] Abnormal bleeding	[ ] Anemia
[ ] Hemophilia	[ ] AIDS
[ ] Blood transfusion	[ ] Arthritis
[ ] Ulcers/Colitis	[ ] Glaucoma
[ ] Heart problems	[ ] Drug addiction
[ ] Epilepsy/Seizures	[ ] Skin problems
[ ]Asthma or Hay fever	[ ] Blood Disorders
[ ] Chemo/Radiation therapy	[ ] Cancer/Tumor
[ ] Diabetes/abnormal blood sugar	[ ] Kidney/Liver disease
[ ] Difficulty breathing	[ ] Hepatitis /Jaundice
[ ] Lung problems	[ ] Emphysema
[ ] High/Low blood pressure	[ ] Rheumatic fever

Please describe any of the above conditions:

_____

_____

APPENDIX V

Do you have a history of allergies to any oral care products, personal care consumer products, or their ingredients?

If yes, please fill explain: _____

Do you take any medications? If yes, please fill out following:
List any prescription or over the counter medications which you are taking:

Name of Medication	Amount taken	How often	Reason

DENTAL HISTORY

Name of your dentist: _____ Phone#: _____

How often do you visit your Dentist_____?

Date of last visit: _____

WOMEN ONLY
Please answer the following:

Are you pregnant? _____**Y**_____ **N** If yes, list due date _____ ;
Are you presently nursing? _____**Y**_____**N**

I understand that the information that I have given today is correct to the best of my knowledge. I also understand that this information will be held in the strictest of confidence, and it is my responsibility to inform this office of any changes in my medical status. I understand that my participation on this study is voluntary and that I terminate my participation in the study at any time.

_____ _____
Signature Date

APPENDIX VI
INITIAL SCREENING FORM

Subject Number: _____ **Subject Initials:** _____ **Gender** [ ] M [ ] F **Age:** _____
Date _____

1. Signed Informed Consent Form YES ___ NO ___
2. Male and female subjects, aged 18-70, inclusive YES ___ NO ___
3. All maxillary anterior teeth must be present; without the presence of crowns/restorations YES ___ NO ___
4. Average VITA Extended BleachedGuide 3D-Master shade of 17 or darker for 6 maxillary anterior teeth YES ___ NO ___
5. Available for the 1-week duration of the study YES ___ NO ___

If answer to any of questions 1-5 is No, subject is ineligible for study. Subject should be dismissed and question 14 below completed. If subject is eligible, continue to questions 6-13.

6. Presence of orthodontic appliances or any anterior tooth with a prosthetic crown or veneer. YES ___ NO ___
7. Obvious signs of periodontal disease, rampant caries, or any condition that the dental examiner considers exclusionary from the study. YES ___ NO ___
8. Five or more carious lesions requiring immediate care.
9. Concurrent participation in an oral clinical study. YES ___ NO ___
10. Self-reported pregnant and/or lactating women. YES ___ NO ___
11. History of allergies to tooth whitening products, hydrogen peroxide, personal care consumer products, or their ingredients. YES ___ NO ___
12. Restorations on the teeth to be scored which may interfere with scoring procedures. YES ___ NO ___
13. Have used professional whitening product within one (1) year and/or had a dental prophylaxis (professional dental cleaning) within thirty (30) days prior to the start of the study. YES ___ NO ___

If answer to any of questions 6-13 is YES, subject is ineligible for study. Subject should be dismissed and Question 14 completed.

14. IS SUBJECT ELIGIBLE FOR ENTRY INTO THE STUDY? YES ___ NO ___

SIGNATURE, EXAMINING DENTIST _____ DATE: _____

APPENDIX VII

ORAL SOFT AND HARD TISSUE ASSESSMENT FORM

SUBJECT NUMBER_____ DATE_____

Circle the time period for this evaluation.

Screening / Entry	1 Week Product Use	2 Weeks Product Use

AREA		NORMAL
1.	Lips	YES ___ NO ___
2.	Soft Palate	YES ___ NO ___
3.	Hard Palate	YES ___ NO ___
4.	Gingival Mucosa	YES ___ NO ___
5.	Buccal Mucosa	YES ___ NO ___
6.	Mucogingival Folds	YES ___ NO ___
7.	Tongue	YES ___ NO ___
8.	Sublingual and submandibular areas	YES ___ NO ___
9.	Salivary glands	YES ___ NO ___
10.	Tonsilar and pharyngeal areas	YES ___ NO ___
11.	Teeth	YES ___ NO ___

If the answer to any of questions 1-11 is **"NO"**, please explain.

_____

_____

_____ _____

Date Examining Dentist Signature

APPENDIX VIII

TOOTH COLOR EXAMINATION FORM

SUBJECT'S INITIALS _____ **DATE**_____ **SUBJECT NUMBER**_____

Circle the time period for this evaluation.

Screening	Baseline	Immediately after whitening	7 days after whitening

UPPER TEETH	TOOTH NUMBER	VITA SHADE GUIDE SCORE	VITA SHADE RANKING SCORE
Right Cuspid	6		
Right Lateral	7		
Right Central Incisor	8		
Left Central Incisor	9		
Left Lateral Incisor	10		
Left Cuspid	11		

_____ _____

Examining Dentist Signature **Date**

APPENDIX IX

Visit Form / End of Study Visit Form

Subject Number _____ **Subject Initials**_____ **Visit:**_____ **Date**_____

Does the patient currently take any medications (including OTC products)? Yes No (Circle One)

If **YES**, please list all medications below:

Medication	Total Daily Dose	Date Started	Date Stopped (circle C if continuing)	Indication
			C	
			C	
			C	

All medications must be reviewed by the clinical study medical/dental supervisor

1. Were there any unexpected or serious reactions since the previous examination? YES NO

2. Was any treatment prescribed for above? YES NO
   If yes, describe _____

3. Was any dental treatment rendered since the previous examination? YES NO
   If yes, describe _____

4. Was any medication prescribed for the subject since the last examination? YES NO
   If yes, describe dose, duration, and reason _____

5. For female subjects: Is the subject pregnant or breast feeding an infant? N/A YES NO

6. Do any of the responses to Questions 1-5 warrant exclusion of this subject's data from the statistical analysis? YES NO
   If yes, explain _____

7. Will the subject continue participation in the study? YES NO

If question 7 is "NO", please complete question 8 below

TO BE COMPLETED BY STUDY PERSONNEL ONLY

8. Did the subject complete the study? YES NO
   If no, explain _____

_____ _____

Examining Dentist Signature Date

APPENDIX X

Form 105361.02 Adverse Event/Reaction Reporting Form for Studies

General Instructions:

- Do **NOT** leave any field blank. – If information is not known or is not available complete a field with Unknown or Not Available (N/A).
- The completed form should be sent within 1 Calendar day (no later than 1 business day) of awareness –
    - By the Investigator to the Study Originator
    - By the Study Originator to:

      1) Global Pharmacovigilance (GPV) at globalpcv@colpal.com &

      2) Safety Clearance Review Process (SCRP) at SCRP@colpal.com

Supplemental Guidance for filling the tables:

1. **Awareness Date-** Colgate-Palmolive –
   Write the date / Select the date from dropdown list when Colgate-Palmolive has first received the report.
2. **Awareness Date- Investigator-**
   Write the date / Select the date from dropdown list when investigator or their delegate has first received the report

   Note: For reporting follow up information, give the dates on which Colgate-Palmolive and Investigator or their delegate became aware of follow up information.

TABLE No. 1, 2, 3, 4 and 5

1) **Study Information** –
   - **State Protocol #** - State the protocol # as given on cover page of protocol
   - **Study title** - State title of the study as given on cover page of protocol
   - **Indication/Objective of Protocol -** Provide objective of the protocol
   - **Type of study** - Tick the appropriate box(s) to indicate if study type is clinical, consumer, panel or combination
   - **Study Originator/Monitor** – Mention the study Originator/Monitor's name and Contact number
   - **Centre Name** - Complete the Centre details such as name and investigator details (E.g. name, contact details, occupation, etc.)

2) Subject Information -
   - **Section A)** Provide demographic details of subject.
   - **Section B)** Complete section **only if** subject is pregnant female.

3) Reporter Information –
   - This section to be filled **only if Reporter is different from Investigator** named in section 1) Study Information
   - **Sender/Reporter Name:** If investigator is reporter mention – "Same as given in Section 1".

If reporter is different than Investigator, mention name and fill rest of the reporter information (Address, country, email, telephone, etc.)

- **Healthcare Professional/non-Healthcare Professional -** Tick the applicable box whether the reporter is a Health Care Professional or not. If Healthcare Professional, specify occupation (Physician, Dentist, Dental Surgeon, Pharmacist, Nurse, Hygienist…).

4) **Phase of study the earliest event (s) occurred during–**
   Mark the appropriate box to specify the phase in which the earliest event occurred (E.g. After consent, wash-out, pre-randomization, randomization, etc.)

5) Study products -

- **Product Name -** Provide information of all products relevant to the study which the subject received (including washout products, test product, blinded, placebo, comparator, etc.).
- **Lot No/Batch No/Serial No (If MOCD)** – Write the batch number that is printed on the pack or outer packaging of product. Serial number is applicable for Mechanical Oral Cleaning Devices (MOCD) like Toothbrushes or Dental Floss.
- **Route of administration** – Provide how the product is used. E.g. oral, topical application
- **Dosage & Frequency** – Provide amount of product used and the frequency of usage.

Dosage examples: pea size, cap full, 10 ml, etc.
Frequency examples: daily, 2 times/day, weekly, at bedtime, etc.

- **Start Date (DD-MMM-YY)** – The date when the subject has started using the study product. Partial dates are accepted (MMM-YY)
- **Stop Date (DD-MMM-YY)** – The date when the subject has stopped using the study product.
- **Action taken with Product** – Select the appropriate action taken after subject experienced the adverse event from the dropdown list. Action could be anyone of these:
  - Withdrawn permanently - Discontinued
  - Withdrawn temporarily - Stopped for some time
  - Dosage decreased - The amount of product used is decreased
  - Dosage increased - Increase in amount of product taken during usage.
  - No Action Taken – Continued as before
  - Unknown - No info provided

- **Death** – In case of death of subject, mention the date and cause of death (if known)
- **Autopsy** – Tick mark to specify if autopsy was done or status is unknown. State the outcome of the autopsy if done.

TABLE No. 6, 7 and 8

5) **Adverse Event (AE)/Reaction Information** – Provide the information related with the adverse events reported.

For non-serious events leave the field blank

- **Seriousness Criteria:** Choose or write any of the below mentioned seriousness criteria for the reported event
  - Death
  - Life-Threatening
  - Hospitalization/Prolongation of hospitalization
  - Persistent or significant disability/incapacity
  - Congenital Anomaly/Birth defect
  - Medically Significant – If AE is mentioned as medically significant by HCP.
  - Suspected transmission - Suspected transmission **via a medicinal product** of an infectious agent
  - Any malfunction or deterioration in the characteristics and/or performance of a medical device, as well as any inadequacy in the labeling or the instructions for use which, directly

or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to any of the other seriousness criteria here above.
- Temporary functional incapacity for Cosmetics (only applicable to studies conducted in EU)

- **Causality** - Tick the most appropriate box based on investigator's assessment.
  - Definite – Adverse event/reaction is incontrovertibly related to study product.
  - Probable - Adverse event/reaction is considered related to study product with a high degree of certainty.
  - Possible – A connection to the study product appears unlikely, but cannot be ruled out with certainty.
  - Unlikely - Adverse event/reaction is considered unrelated to study product.
  - Not related - Adverse event/reaction is clearly and uncontrovertibly due to causes other than the study product.

- **Severity** – Tick the most appropriate box.

- **Outcome** – Select the outcome of the adverse event from the dropdown list.
  - Fatal - The event resulted in death of subject.
  - Recovered - If AE is resolved.
  - Recovered with Sequelae - The AE has resolved, but subject still experiences effects of the event (e.g. subject suffered a stroke and continues to have right arm weakness).
  - Recovering - when the AE is resolving slowly
  - Continuing/ Ongoing -- If event is still present at the time of reporting.
  - Unknown – No information was provided

- **Death** – In case of death of subject, mention the date and cause of death (if known)
- **Autopsy** – Tick mark to specify if autopsy was done or status is unknown. State the outcome of the autopsy if known..

- **Describe event (s)/reactions(s) in detail:** Provide the description of events in sequence as occurred. Including treatment received.
- **Protocol status of subject** – Tick the appropriate box to specify if subject is continued/discontinued in the study.
- **Was the subject treated for the event(s)/reaction(s) (Medical Intervention)?** Tick as yes or no depending on if the subject was treated for the adverse event experienced. If yes, specify the treatment given.
- **Event/Reaction abated after study product(s) stopped or dose reduced?** Provide information as Yes, No or N.A. if the event/reaction subsided on stopping or reducing the dose.
- **Event/Reaction reappeared after study product(s) reintroduced?** Provide information as Yes, No or N.A. if the event/reaction reappeared on reintroducing the dose.

7) **Subject Medical History** – Include information on any past medical illness, condition, or surgeries. If there is no past medical history select the "None" checkbox. If no medical history was provided select the "Unknown" checkbox.
8) **Other Medications/ Products used simultaneously** -Provide information of all other medications or products the subject used or was exposed to during or prior to the onset of AE.
9) **Laboratory data & other test procedure(s) relevant to the AE(s)** - Include information on laboratory data and other test procedures those are relevant to the AE(s).

Protocol No: CRO-2025-09-WHT-MS

U.S.IRB
OCT - 7 2025
"APPROVED"

Instructions: Refer to the General Instructions & Supplemental Guidance pages for specific details on completing sections of the form. Additional pages may be added, if necessary, to report all information.

Awareness date – Colgate-Palmolive:	Awareness Date- Investigator:
1) Study Information	
Protocol #:	Centre Name:
Study Title:	Investigator:
Indication /Objective of Protocol:	Address:
Study Type: ☐Clinical Trial (Interventional) ☐Consumer ☐Panel ☐ Other Clinical ☐ Other Specify	Tel.: Fax:
Study Originator/Monitor: Contact #	Email: Health Care Professional : ☐ Yes ☐No Specify occupation:

2) Subject Information				
A)	ct's ID #: Initials:	**Gender** ○ Male ○ Female	Age/(Age Group): Or Date of Birth: - -	Weight ○ LB ○ KG
B)	ect is pregnant, how many months?			

3) Reporter Information ***(Complete only if different from Investigator named above)***	
Sender/Reporter Name:	
Address	Country:
Email:	Telephone: Fax:
☐ Healthcare Professional Specify occupation:	☐ Non-Healthcare Professional
4) Phase of study the earliest event (s) occurred during:	

☐ After consent ☐ Wash-out ☐ Pre-randomization ☐ Randomization: no product

☐ Randomization: product exposure ☐ Other:

5) Study products (Please indicate if Test product, Blinded Product, Comparator (control product) or Placebo wa used by subject)

Product Name	**Lot No/ Batch No/ Serial No (If MOCD)**	**inistration**	**Dosage & Frequenc y**	**Start Date** (DD-MMM-YYYY)	**Stop Date** (DD-MMM-YYYY)	**Action taken with Product**
				-	-	
				-	-	
				-	-	
				-	-	

6) Adverse Event/Reaction Information

Adverse Events (AEs)	**St Date of AEs** MMM-YYYY)	**Date of AEs** MMM-YYYY)	**sness Criteria**	**Causality**	**Severity**	**Outcome**
	-	-	Choose an item.	☐ Definite ☐ Probable ☐ Possible ☐ Unlikely ☐ Not Related	☐ Mild ☐ Moderate ☐ Severe	
	-	-	Choose an item.	☐ Definite ☐ Probable ☐ Possible ☐ Unlikely ☐Not Related	☐ Mild ☐ Moderate ☐ Severe	

	-	-	Choose an item.	☐ Definite ☐ Probable ☐ Possible ☐ Unlikely ☐Not Related	☐ Mild ☐ Moderate ☐ Severe	
	-	-	Choose an item.	☐ Definite ☐ Probable ☐ Possible ☐ Unlikely ☐Not Related	☐ Mild ☐ Moderate ☐ Severe	
	-	-	Choose an item.	☐ Definite ☐ Probable ☐ Possible ☐ Unlikely ☐Not Related	☐ Mild ☐ Moderate ☐ Severe	
	-	-	Choose an item.	☐ Definite ☐ Probable ☐ Possible ☐ Unlikely ☐Not Related	☐ Mild ☐ Moderate ☐ Severe	
	-	-	Choose an item.	☐ Definite ☐ Probable ☐ Possible ☐ Unlikely ☐Not Related	☐ Mild ☐ Moderate ☐ Severe	
	-	-	Choose an item.	☐ Definite ☐ Probable ☐ Possible ☐ Unlikely ☐Not Related	☐ Mild ☐ Moderate ☐ Severe	

Death (dd/mmm/yyyy): **Cause of death if known:**	**Autopsy:** ☐ NO Outcome:

Describe event (s)/reactions(s) in detail:

Protocol status of subject:	
☐ Subject continued in protocol	☐ Subject discontinued from protocol
☐ Unrelated	☐ Unrelated
☐ Unable to assess Subject continued in protocol	☐ Unable to assess Subject discontinued from protocol

Was the subject treated for the event(s)/reaction(s) (Medical Intervention)?

☐ **YES** ☐ **No**

If yes, please specify or describe:

Event/Reaction abated after study product(s) stopped or dose reduced?

☐ YES	☐ NO	☐ N.A.

Event/Reaction reappeared after study product(s) reintroduced?

☐ YES	☐ NO	☐ N.A.

7) Subject Medical History : ☐ **None** ☐ **Unknown** ***(Provide the medical history including pre-existing medic conditions)***

8) Other Medications/ Products used simultaneously: ☐ **None** ☐ **Unknown**

Other Medications/ Products	**Date** (DD-MMM-YYYY)	**Date** (DD-MMM-YYYY)	**Indication**	**Dosage & Frequency**	**Route of administration**
	-	-			
	-	-			
	-	-			
	-	-			
	-	-			
	-	-			

9) Laboratory data & other test procedure(s) relevant to the AE/AER(s)

Test	**Date (dd/mmm/yyyy)**	**Result (Specific value, normal, abnormal, clinically significant)**

Investigator/Designee Signature:	**Date** (dd/mmm/yyyy)**:**

APPENDIX X

Form 105362.02 Periodic/End of Study Report Form for Studies on Humans

Instructions :

- For Periodic reporting (study lasting >1 month):
  - Complete monthly with all *serious and non-serious adverse reactions* reported.
  - Submit monthly to Study Originator if form is completed by an individual other than the Study Originator/Manager.
  - Study Originator submits form monthly to globalpcv@colpal.com and scrp@colpal.com
- For End of Study reporting:
  - Complete upon study completion with all *serious and non-serious adverse events (AE) and adverse reactions (AR)* reported. If no AE/AR is reported, form must be completed indicating such information.
  - Submit within 2 weeks of study completion to Study Originator if form is completed by an individual other than the Study Originator.
  - Study Originator submits form within 2 weeks of receipt or study completion to globalpcv@colpal.com and scrp@colpal.com
- All dates must be in dd/MMM/yyyy format (e.g. 01Dec1980).
- All fields in **Section A** must be completed. If information is unknown, please record "Unknown" in field. If field is not applicable, please record "N/A".
- **Section C Guidance:**
  - If a subject experienced multiple adverse events or reactions, record only 1 event/reaction per row in table.
  - Causality: This is an assessment of the relationship between study product use and the adverse event/reaction experienced. Based on assessment, note in field one of the following:
    - Definite – Adverse event/reaction is incontrovertibly related to study product.
    - Probable - Adverse event/reaction is considered related to study product with a high degree of certainty.
    - Possible – A connection to the study product appears unlikely, but cannot be ruled out with certainty.
    - Unlikely - Adverse event/reaction is considered unrelated to study product.
    - Not related - Adverse event/reaction is clearly and uncontrovertibly due to causes other than the study product.
  - Severity: This is the investigator's assessment of the adverse event/reaction intensity. Note in field either "mild", "moderate", or "severe".
  - Serious: Note "Yes" if adverse event/reaction resulted in hospitalization/hospitalization was prolonged, temporary/permanent disability, congenital anomaly, was life threatening, fatal or medically significant. Note "No" if none of the prior criteria is met.

- Other Products Used: Note any products used concomitantly with the study product (e.g. medications, other personal care products, etc.).
- Outcome with Date: Note either "Resolving", "Resolved", "Resolved w/Sequelae", "Not Resolved", "Fatal", or "Unknown". Provide date if adverse event/reaction is resolved or fatal.
- Comments: Please note any additional relevant clinical information (e.g. medical history, diagnostic tests, treatment received due to event/reaction, etc.).

Section A: Study Information	
Study Title:	Study Type: Clinical ☐ Consumer ☐ Panel ☐ Other ☐ Specify if selecting Other:
Protocol #:	Ref #:
Indication/Objective of Protocol:	
Primary Study Product/PDM#:	
Study Start Date (dd/MMM/yyyy):	Country where study was conducted:
Investigator Name:	Study Originator Name:

Investigator/ Designee Signature: _____ Date dd/mmm/yyyy: _____

Section B: Report Type

Check applicable report type

☐ Periodic Report

☐ End of Study report

Were any adverse events/reactions reported during the study? If 'Yes' is checked, please complete section C

☐ Yes ☐ No

Section C: Adverse Event/Reaction Information

Protocol #: Investigator Name:

Complete the table below *only* if an adverse event/reaction was reported during the study.

Case ID No.	Study Site Award e Date	Subject Information			Study Product Information			Adverse Events/Reactions				Other Products Used	Outcome with Date	Comments
		ID No.	Age/Date of Birth	Gender	Product Name	Dose & Frequency	Duration of Use	Description	Causality	Severity	Serious (Yes/ No)			

Note: If needed attach additional pages of Section C to document all events/reactions reported during the study.

APPENDIX XI
LABEL INSTRUCTIONS

LABEL INSTRUCTIONS FOR TOOTHBRUSH AND TOOTHPASTE

Toothbrush and Toothpaste will be placed in a ziploc bag with a label applied to the outside of the bag

CRO-2025-09-WHT-MS

Product (Letter Code)

Brush your teeth twice daily (morning and evening) for two (2) minutes each time.
Cover the entire length of the bristled head with toothpaste. Do not swallow.
For investigational use only by the study participant. Not for Retail Sale.
For Adult Use Only. Keep out of reach of children under 6 years.
In case of emergency or for further information telephone:
Dr. John T. Gallob at 702-885-6984

LABEL INSTRUCTIONS FOR IN-OFFICE PROFESSIONAL WHITENING

CRO-2025-09-WHT-MS

Product (Letter Code)

Follow manufacturer's instructions, detailed in appendix XII.

For investigational use only by a dental professional. Not for Retail Sale.
For Adult Use Only. Keep out of reach of children under 6 years.
In case of emergency or for further information telephone:
Dr. John T. Gallob at 702-885-6984

APPENDIX XII

PRODUCT APPLICATION GUIDELINES

Beaming White - 25%HP Gel

Summary of Professional Whitening Application

Proper isolation of soft tissues is crucial to prevent irritation and chemical burns. The treatment typically consists of three 15-minute sessions, with careful monitoring of patient comfort and progress. Post-treatment care and maintenance instructions are provided to the patient to maximize and prolong results.

1. Preparation of Materials

• Remove the whitening syringe from refrigeration and allow it to reach room temperature before use.

•Confirm that both the clinician and patient are protected with protective eyewear and barrier clothing. This safeguards against any incidental contact with whitening gel.

2. Syringe Preparation

•Detach the clear cap from the whitening syringe and securely twist on the applicator tip.

•Prime the tip by dispensing a small amount of gel onto cotton or a gauze pad. This confirms a smooth flow; if resistance is encountered, replace the tip to maintain precision delivery.

3. Cheek Retraction – OptraGate® Placement — tooth & Gingiva Preparation

•Gently stretch the patient's lips and insert the OptraGate cheek retractor, starting with the lower arch. Guide the lower lip flange into position first, then flex the upper flange into place.

•Ensure the retractor sits comfortably, creating a clear, unobstructed field with lips and cheeks fully retracted.

•Verify that the OptraGate is stable without pinching soft tissue.

•Thoroughly rinse and air-dry the teeth and surrounding gingiva. A dry, contaminant-free surface is essential for both barrier adhesion and gel activity.

4. Gingival Barrier Application

•Securely attach the dispensing tip to the barrier syringe and confirm flow.

•Beginning one tooth distal to the most posterior tooth being treated, trace a continuous, even bead of barrier material directly along the gingival margin. Extend the bead approximately 0.5 mm onto the enamel to ensure complete coverage and seal.

•Bridge interproximal spaces: In open embrasures, sweep the barrier upward to create a seal that prevents gel seepage while maintaining a natural contour.

•Continue along the full arch, overlapping slightly with the initial bead to ensure continuity and protection.

5. Polymerization of Barrier

•Light-cure the barrier for ~20 seconds per arch using a slow, scanning motion, rather than fixed-point curing. This distributes energy evenly and prevents localized overheating.

•After curing, gently probe the barrier with a blunt instrument. The goal is to feel for a firm, non-tacky surface while confirming marginal adaptation—without disturbing the seal.

6. Gel Application

•Apply a uniform layer of whitening gel (0.5–1 mm thickness) directly to the labial surfaces of the teeth being treated.

•Avoid excess gel to reduce risk of seepage beyond the barrier.

7. Light Activation

•Connect the magnet power tether to the LED handpiece.

•Position the whitening tray into the mouth and activate the device.

•Allow the treatment cycle to run for 15 minutes without interruption.

8. Gel Removal

•At completion, safely evacuate the gel using a surgical suction tip. Do not employ traditional water suctioning, as this may aerosolize or splatter gel.

•Once the visible bulk is removed, perform a gentle, controlled rinse and air-drying, taking care not to disturb the gingival barrier.

9. Repeat Whitening Cycles

- Repeat steps 6–8 for two additional cycles, each consisting of:
- 0.5–1 mm gel application
- LED activation for 15 minutes
- Controlled suction and rinse removal

10. Barrier Removal

•After the final rinse, gently insert a fine dental instrument beneath the cured barrier margin and slide along the gingival contour, lifting the barrier in sections rather than pulling abruptly.

•Remove any interproximal remnants with floss or a scaler for a clean finish.

11. Shade Evaluation

•Perform a final thorough rinse and air-dry.

•Compare pre- and post-treatment shade using a standardized shade guide.

•Document results with clinical notes and photographs for accurate record-keeping.

Test Cell 1

TECHNIQUE GUIDE

Preparation of Materials

1

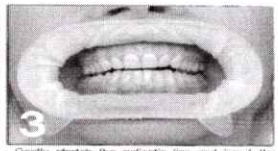
- Remove the whitening gel syringes (hydrogen peroxide–based) from refrigeration 15–30 minutes prior to treatment. This allows the gel to reach room temperature and ensures optimal flow and effectiveness.

- Confirm that both the clinician and patient are protected with protective eyewear and barrier clothing. This safeguards against any incidental contact with whitening gel.

2

- Detach the clear cap from the whitening syringe and securely twist on the applicator tip.

- Prime the tip by dispensing a small amount of gel onto cotton or a gauze pad. This confirms a smooth flow; if resistance is encountered, replace the tip to maintain precision delivery.



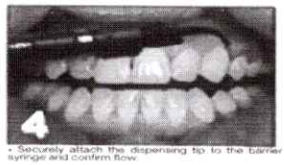
3

- Gently stretch the patient's lips and insert the OptraGate cheek retractor, starting with the lower arch. Guide the lower lip flange into position first, then flex the upper flange into place.

- Ensure the retractor sits comfortably, creating a clear, unobstructed field with lips and cheeks fully retracted.

- Verify that the OptraGate is stable without pinching soft tissue.

- Thoroughly rinse and air-dry the teeth and surrounding gingiva. A dry, contaminant-free surface is essential for both barrier adhesion and gel activity.



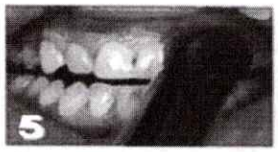
4

- Securely attach the dispensing tip to the barrier syringe and confirm flow.

- Beginning one tooth distal to the most posterior tooth being treated, trace a continuous, even bead of barrier material directly along the gingival margin. Extend the bead approximately 0.5 mm onto the enamel to ensure complete coverage and seal.

- Bridge interproximal spaces. In open embrasures, sweep the barrier upward to create a seal that prevents gel seepage while maintaining a natural curvature.

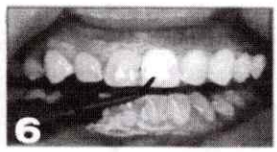
- Continue along the full arch, overlapping slightly with the initial bead to ensure continuity and protection.



5

- Light-cure the barrier for ~20 seconds per arch using a slow, scanning motion, rather than fixed-point curing. This distributes energy evenly and prevents localized overheating.

- After curing, gently probe the barrier with a blunt instrument. The goal is to feet for a firm, non-tacky surface while confirming marginal adaptation—without disturbing the seal.



6

- Apply a uniform layer of whitening gel (0.5–1 mm thickness) directly to the labial surfaces of the teeth being treated.

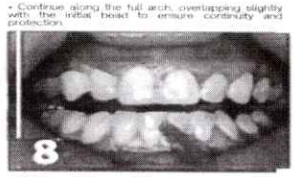
- Avoid excess gel to reduce risk of seepage beyond the barrier.

7

- Connect the magnet power tether to the LED handpiece.

- Position the whitening tray into the mouth and activate the device.

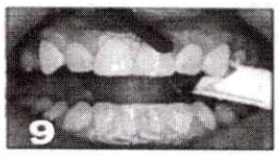
- Allow the treatment cycle to run for 15 minutes without interruption.



8

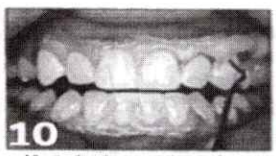
- At completion, safely evacuate the gel using a surgical suction tip. Do not employ traditional water suctioning, as this may aerosolize or splatter gel.

- Once the visible bulk is removed, perform a gentle, controlled rinse and air-drying, taking care not to disturb the gingival barrier.



9

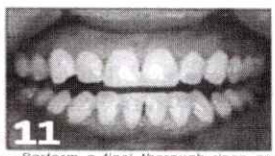
- Repeat steps 6-8 for two additional cycles, each consisting of:
  - 0.5–1 mm gel application
  - LED activation for 15 minutes
  - Controlled suction and rinse removal



10

- After the final rinse, gently insert a fine dental instrument beneath the cured barrier margin and slide along the gingival contour, lifting the barrier in sections rather than pulling abruptly.

- Remove any interproximal remnants with floss or a scaler for a clean finish.



11

- Perform a final thorough rinse and air-dry.

- Compare pre- and post-treatment shade using a standardized shade guide.

- Document results with clinical notes and photographs for accurate record-keeping.

Protocol No: CRO-2025-09-WHT-MS

Philips Zoom Chairside Light-Activated Whitening System - 25% HP Gel

Summary of Professional Whitening Application

Proper isolation of soft tissues is crucial to prevent irritation and chemical burns. The treatment typically consists of multiple 15-minute sessions, with careful monitoring of patient comfort and progress. Post-treatment care and maintenance instructions are provided to the patient to maximize and prolong results.

I. Pre-Treatment Preparation

- **Gel Preparation:**
  - Remove whitening gel syringe from refrigeration at least 6 hours before use (preferably overnight) to allow it to warm to room temperature and thicken.
  - If immediate use is required, place the syringe in a cup of hot water (49°C) for 10 minutes, then remove and wait 5 minutes before extruding gel.

II. In-Office Whitening Treatment

1. **Light Guide & Accelerator Setup:**
   - Remove the light guide from its packaging and place it on the LED Accelerator.
   - Switch on the LED Accelerator using the power button. Ensure "Guide Status - Guide Attached" displays.
2. **Suction & Eye Protection:**
   - Place the surgical suction tip on the high vacuum suction.
   - Place the Zoom! protective eyewear on the patient.
3. **Retractor Placement:**
   - Insert the IsoPrep retractor at an angle, retracting one side at a time, using a dental mirror to assist. (Note: The retractor is specifically engineered for this system; do not substitute).
4. **Before Photo:**
   - Take a retracted "before" photo using a matched shade tab.
5. **Patient Positioning:**
   - Fully recline the patient.
6. **Isolation (Cotton Rolls & Gauze):**
   - Place cotton rolls in the center of the upper and lower vestibules. If too large, unfold gauze and twist like a cotton roll. (Note: Do not substitute gauze; the provided gauze offers superior protection).
   - Fully open gauze squares and fold into triangles. Place the apex into the posterior cheek, tuck the material into the cheek, and secure ends between cotton rolls and retractor.
7. **Face Bib:**
   - Carefully place one face bib around the retractor, one side at a time. Add an additional bib for heavy salivators.
8. **Liquidam Application (Gingival Barrier):**
   - Remove Liquidam syringe from packaging, twist to remove cap, and attach metal tip.
   - Dry soft tissue thoroughly.

- Scallop barrier material to the CEJ area (gingival margins) on upper teeth, slightly overlapping enamel and interproximal spaces to form an enamel seal.
- Cure Liquidam with a curing light for about 10 seconds, sweeping across the arch. (Note: Liquidam may warm; ensure even light distribution).
- Change to plastic tip. Fill from cotton roll to the cured Liquidam line, curing completely. Ensure all interproximal areas are covered, leaving no soft tissue exposed.
- Apply Liquidam to the lower arch using the same method. Press lightly to ensure complete cure (material should be solid).
- If necessary, re-cure for an additional 5 seconds.
- Extend Liquidam distally at least one tooth beyond the whitening area, ensuring 2mm thickness.
- **"No Pink" Rule:** Ensure exposed dentin and tissue are covered by barrier material. No pink tissue should be visible.

9. **Whitening Gel Application:**
   - Remove cap from room temperature whitening gel syringe. Attach mixing tip by aligning marks and twisting one-quarter turn clockwise.
   - Using the provided blue brush, apply whitening gel (1-2mm thick) to the patient's teeth.
   - Use caution not to disturb the barrier material. Prolonged exposure can cause gingival irritation.
   - (Note: Small air gaps/bubbles in syringe are normal due to degassing; purge until both sides extrude gel if air is near the front).
   - (Note: Slight yellow/pink coloring of gel is normal manufacturing byproduct and does not affect peroxide content or performance).
10. **Patient Positioning for Light Activation:**
    - Once gel application is complete, raise the chair back to a slightly reclined position (approx. 45-degree angle) to allow comfortable swallowing while maintaining light pressure on the bite block.
11. **LED Accelerator Positioning:**
    - Slide the LED Accelerator into place next to the patient. Ensure the arm is movable but stable.
    - Position the LED Accelerator head by aligning the slots on the light guide with the retractor. (Note: Light guide ensures correct distance and alignment for optimal light exposure).
12. **Light Activation & Session Monitoring:**
    - Follow display prompts to switch on the light and activate the timer. A countdown will display.
    - Light will emit from the arrow point and illuminate the patient's teeth. Light flicker in first few seconds is normal.
    - The LED Accelerator will beep once at 3 minutes remaining and three times in the final 3 seconds of the 15-minute session. A long beep indicates session completion and light turns off.
    - (Note: To pause, press "Pause" button; remaining time flashes. Press "Pause" or "Start" to reactivate).

- Inform patient that session progress is tracked by four white lights on top of the LED Accelerator head (each light is one-quarter of a session).
- (Note: During 15-minute sessions, ensure patient has means of communication and is not left unattended).

13. **Post-Session & Gel Removal:**
    - After each session, gently pull the LED Accelerator away from the patient, being careful not to dislodge isolation materials.
    - Carefully remove whitening gel with a surgical suction tip and/or wipe enamel surface clean with damp gauze. Do not irrigate to avoid dislodging barrier.
    - Check isolation materials for "no pink" tissue. Replace or add if needed.
    - Repeat steps for remaining sessions.
    - (Note: For sensitive patients, lower LED Accelerator intensity; this may result in a fourth 15-minute session).
    - (Tip for sensitivity: Apply Relief ACP oral care gel to lingual surfaces for remaining sessions).
14. **Final Session Completion:**
    - When all sessions are complete, "Sessions Complete" will display for 3 seconds, followed by "Guide Status - Replace Guide."
    - Detach light guide from IsoPrep retractor and pull LED Accelerator away from patient.
    - Suction or wipe remaining whitening gel from teeth. Moisten gauze and cotton rolls and remove isolation materials. Floss to remove interproximal barrier material.
15. **After Photo & Shade Assessment:**
    - Reinsert the retractor and take a retracted "after" photo with the lighter shade tab.
    - Measure shade change by counting the shade shift according to the value-ordered shade guide.

III. Post-Treatment Care and Maintenance

- **Maximizing Results:**
    - Advise patient not to consume coffee, tea, red wine, or tobacco for two hours after treatment, until salivary pellicle reforms.
    - Advise not to drink or eat for 30 minutes after application for best results.
- **Storage:**
    - Store whitening gel between 2°C and 10°C. Temperatures above 10°C will reduce shelf life.

Opalescence Boost PF - 40%HP Gel

Summary of Opalescence Professional Whitening Application

Proper isolation of soft tissues is paramount. The procedure involves meticulous preparation, mixing of the gel, precise application, and careful removal, followed by patient education on post-treatment care and maintenance for optimal, lasting results.

I. Pre-Treatment Preparation

- **Gel Preparation & Mixing:**
  - Bring the 2-barrel syringe to room temperature before mixing.
  - Ensure syringes are securely attached.
  - Depress the small clear plunger into the middle clear syringe to rupture the internal membrane and combine whitener and activator.
  - Push all contents into the clear syringe by pressing the red syringe plunger.
  - Push the contents of the clear plunger completely back into the red syringe.
  - To thoroughly mix, continually push the stems back and forth, mixing 25 times each side.
  - Push all mixed gel into the red syringe.
  - Twist to separate the two syringes and securely attach the recommended tip (Black Mini tip) onto the red syringe.
  - Verify gel flow, consistency, and ensure the gel is **red** before applying intraorally. If resistance is met or the gel is not red, do not use and re-check mixing steps.
  - **Note:** Opalescence Boost 40% should be used within 10 days of mixing. Keep refrigerated between uses.

II. In-Office Whitening Treatment

1. **Isolation (OpalDam™ Resin Barrier - Recommended):**
   - Remove Luer lock cap from the OpalDam resin barrier and securely attach the recommended delivery tip.
   - Verify flow prior to applying intraorally.
   - Rinse and dry teeth and gums thoroughly.
   - Place Ultradent IsoBlock™ bite block and self-supporting lip/cheek retractors (or Ultradent Umbrella™ retractor) to avoid contact with soft tissue.
   - Apply OpalDam resin barrier along the gingival margin, overlapping approximately 2-3mm onto the enamel. Begin and finish one tooth beyond the most distal tooth being whitened.
   - Express resin through any open embrasures onto the lingual tissue to completely seal and cover exposed papilla.
   - Use a mouth mirror to ensure no gaps exposing underlying gingiva; apply resin to any gaps.
   - Light cure OpalDam for 20 seconds per arch using a scanning motion. When isolating a single tooth, scan for 5 seconds. Carefully check resin cure with an instrument.

- **Note:** If improper soft tissue isolation leaves patient's soft tissue exposed to peroxide gel, immediately wipe the gel from the tissue, rinse the area well. Tissue should return to normal within 20-30 minutes. If chemical irritation occurs, administer a nonsteroidal anti-inflammatory drug (NSAID) as per instructions.

2. **Isolation (Rubber Dam - Alternative):**
   - Place rubber dam to isolate the teeth being whitened.
3. **Eye Protection:**
   - Patient and dental professional **must** wear protective eyewear with side shields when handling the product.
4. **Whitening Gel Application:**
   - Apply a 0.5-1.0mm thick layer of the mixed red gel to the labial surface of the tooth/teeth to be whitened.
   - Allow gel to remain on the teeth for **20 minutes** per application, periodically checking patient comfort and suctioning saliva.
   - **Note:** Avoid direct contact of the active gel surface with gums and/or salivary flow.
5. **Gel Removal (Post-Application):**
   - Suction gel from teeth using a Luer Vac and SST™ (Surgical Suction Tip) or a surgical suction tip. **Do not use water** while suctioning gel to avoid splatter.
   - When no gel is visible, lightly rinse and air dry. Use caution not to dislodge the isolation barrier or rubber dam seal.
6. **Session Repetition & Monitoring:**
   - Evaluate shade change after each application.
   - Monitor patient for sensitivity and irritation. If persistent sensitivity occurs, discontinue use.
   - Repeat application steps for no more than **3 applications per visit** if desired results have not been achieved.
7. **Final Cleanup:**
   - Suction gel from the tooth surface and access opening using the Luer Vac and SST (Surgical Suction Tip) or a surgical suction tip.
   - When no gel is visible, lightly rinse and air dry. Use caution not to dislodge the isolation barrier or rubber dam seal.
   - Follow "Clean-up" instructions to remove gingival barriers.

III. Post-Treatment Care and Maintenance

- **Disposal:**
  - Dispose of waste according to local rules, guidelines, and regulations.
  - Before disposing of syringes, aspirate water into the syringe and express liquid down the drain multiple times.
  - Ensure any used gauzes are rinsed with water before disposal.
- **Storage:**
  - Store according to the outer package label.
  - Keep out of reach of children.

APPENDIX XIII

Patient Questionnaire

Study CRO-2025-09-WHT-MS

Product Code : _____

ID#: _____

Questionnaire for the Patient Receiving the Treatment

- **Baseline :** Take a look at your teeth before treatment starts without the gingival barrier.
- **After 3rd Treatment (Gingival Barrier and Cheek Removed) - to be filled out by the patient themselves**

1. Did you notice your teeth got whiter after the 3rd treatment? (circle one)
   Yes
   No

2. Did you experience any sensitivity? (circle one)
   Yes - (a Little, a Moderate amount , a Lot) - if yes, circle how much
   No - skip to Q3

2a. Where did you experience the sensitivity? Circle all that apply
   Teeth
   Gums
   Other (specify) : _____)

3. Did you find the entire experience comfortable? (circle one)
   Yes
   No - please indicate what was not comfortable about the experience?

- **After 1 Week to be filled out by the patient**

1. Are you happy with the whitening results after 1 week? (circle one)
   Yes
   No

2. Do you have any prolonged sensitivity? (circle one)
   Yes
   No

3. Would you recommend this treatment to a friend/family? (circle one)
   Yes
   No

3a. Why or why not?

Study CRO-2025-09-WHT-MS

Product Code : _____

ID#: _____

Questionnaire for the Dental Professional Administering the Treatment

- **After 3rd Treatment**

1. Are you happy with the patients' whitening results after the 3rd treatment? (circle one)
   Yes
   No

2. How would you describe the overall process? (circle all that apply)

   Quick and easy
   Easy to understand how to use
   Easier to use than other in-office whitening systems

Questionnaire for the Dental Professional Administering the Treatment

- **After 1 Week**

1. Are you happy with the patient's whitening results after 1 week? (circle one)

   Yes
   No