

TITLE: An Evaluation of Tangible Boost Replenishing System for Patients with Stevens Johnson Syndrome, Sjögren's Syndrome, and Graft Versus Host Disease

PROTOCOL NUMBER: DOC-55 (previously STM-0856 rev A)

DATE: 01-03-2020

SPONSOR:

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1.0 Objectives

The goal of this research is to determine if the Tangible Boost system adequately replenishes the Hydra-PEG coating on the surface of a rigid contact lens. Hydra-PEG is a coating for soft and rigid contact lens, primarily composed of [REDACTED]

[REDACTED] The Hydra-PEG coating is intended to improve wettability and comfort with contact lenses and is currently FDA approved on a number of contact lenses. Lens cleaning and blinking can lead to diminished benefits of the Hydra-PEG coating over time. For patients with Stevens Johnson Syndrome (SJS), Sjögren's Syndrome (SS), or Graft versus Host disease (GVHD), diminished efficacy of the Hydra-PEG coating can lead to significant decline in satisfaction with the lenses.

Tangible Science, the company that produces Hydra-PEG, has recently developed a new product called Tangible Boost, intended to be used every 30 days and replenish the coating on the surface of the Hydra-PEG treated gas permeable lenses. Essentially, Tangible Boost solution is the Hydra-PEG coating, it is just a solution that can be used at home by the subjects after the initial Hydra-PEG is applied at the lens manufacturing lab. The Tangible Boost kit consists of two unit dose Hydra-PEG solutions (components A and B), as well as a barrel case. The lens wearers are instructed to empty the two vials into the case and soak their lenses for 30 minutes every 30 days to replenish the coating. This product configuration has been optimized to facilitate ease of use for the patient. The method of use for Tangible Boost is similar to that of Menicon's Progent, a two-component cleaning solution for gas permeable lenses.

During this study, patients will use Tangible Clean, an FDA-approved multipurpose solution, for daily cleaning, disinfection, and storage of their lenses.

This is a prospective study to evaluate the efficacy of Tangible Boost to replenish the Hydra-PEG coating on rigid gas permeable contact lenses for patients with SJS, GVHD, and SS. Outcomes from this patient population will be compared to patients with dry eye disease.

We hypothesize that the Tangible Boost replenishing system will re-build the Hydra-PEG coating that was naturally worn away from the contact lens surface over time, and improve the comfort and visual performance of Hydra-PEG coated rigid gas permeable lenses. We anticipate that this be shown by improved patient symptoms and lens wettability after treatment with Tangible Boost, and that this improvement will be particularly pronounced in patients with severe ocular surface disease.

2.0 Background

Gas permeable rigid contact lenses are commonly used as refractive treatment, for normal individuals, but also specifically for individuals with irregular ocular surfaces that require the rigid lens material to mask irregularities on the front refracting surface of their eye (the cornea). However, rigid lenses rely on surface treatments and coatings to improve their interactions with the front surface of the eye and the tear film, as the sensitive tissues can respond negatively to the rigid materials (for example: discomfort, dryness). Several studies have found that reducing the friction between the lens and the surface of the eye (as well as the eyelid) will improve the

comfort of the lenses while a patient is wearing them. Hydra-PEG (Tangible Science, Menlo Park, CA) is a contact lens coating designed to improve the lens/ocular surface interface by mimicking the natural tear film's water content and wettability. The primary principle behind Hydra-PEG coating and Tangible Boost replenishing system is the reduction friction between the lens and the eye surface and eyelids.

Contact lens manufacturers and distributors are continuously developing new products and technology to make the surface of a contact lens more compatible with the ocular surface. Many lenses with the Hydra-PEG coating have been FDA approved and are available in the US and throughout the world, and the Tangible Boost treatment being evaluated here is an important component of maintaining this treatment of the lens surface.

Knowledge gained by this work will increase our understanding of the surface characteristics of rigid lenses and the interaction of the lens surface with the ocular surface in patients with SJS, SS, or GVHD.

3.0 Inclusion and Exclusion Criteria

The participant will be eligible to participate if the following criteria apply: 1. Written Informed Consent has been obtained prior to any study-related procedures taking place; 2. Written documentation has been obtained in accordance with the relevant county and local privacy requirements, where applicable; 3. Male or female, 18 years of age and older prior to the initial visit; 4. Is a new or established wearer of PROSE lenses with optimized lens fit prior to enrollment in the study; 5. Has been diagnosed with Dry Eye Syndrome, SJS, SS, or GVHD 6. In the opinion of the investigator, the subject has the ability to follow study instructions; 7. In the opinion of the investigator, the subject has the ability to complete all study procedures and visits.

The participant would not be eligible to participate if at least one of the following criteria is met: 1. Is aphakic (i.e., missing their natural lens inside the eye); 2. Is currently participating in any other type of eye-related clinical or research study; 3. Is pregnant or nursing as reported by the subject. 4. Has a condition or is in a situation which, in the investigator's opinion, may put the subject at significant risk, may confound study outcomes, or may significantly interfere with the subject's participation in the study. 5. Has a known and self-reported allergy to the following substances: polyethylene glycol, polyvinyl alcohol, triethanolamine, polyquaternium-1, or edetate disodium, which are components of the Tangible Boost and Hydra-PEG systems or care regimen. 6. Has had previous ocular surgery within the past 12 weeks.

The following special populations will be excluded from this study:

- Adults unable to consent (including adults unable to read and understand English)
- Individuals who are not yet adults (infants, children, teenagers)
- Pregnant women
- Prisoners
- Employees of BostonSight

4.0 Vulnerable Populations

The following special populations will be excluded from this study:

- Adults unable to consent (including adults unable to read and understand English)
- Individuals who are not yet adults (infants, children, teenagers)
- Pregnant women
- Prisoners
- Employees of BostonSight

5.0 Number of Subjects

A maximum of 50 subjects will be enrolled in this study.

We expect about a 10% drop-out rate, so we'll expect to recruit approximately 45-50 subjects; and the first 40 to be eligible and complete the study will be used for data analysis. Approximately half of subjects will receive Tangible Boost and half of subjects will receive a placebo kit.

This is a low risk study. We chose 40 subjects to allow for an increased likelihood of reaching significance values with a moderate sample size. Further studies with larger sample sizes will likely be indicated if variability is high among the outcomes.

6.0 Recruitment Methods

Recruitment will begin once IRB approval has been received and will occur through BostonSight. The subject pool will consist of patients who are actively coming through the clinic. We anticipate that all our subjects will be from the current patient population at BostonSight. If a patient is interested in participating in the study, they will be directed to the principal investigator or the study coordinator who will go over the study and ask the screening questions. If they are eligible based on the screening criteria, they will be invited for Visit 1 of the study. If the person calls to learn about the study the investigator or coordinator will use the outline to determine initial eligibility. Current patients of BostonSight may also be recruited as a result of a search of the patient database. A partial HIPAA waiver is requested to permit the investigators to use the database to identify prospective patients.

7.0 Multi-Site Research Communication – N/A

8.0 Study Timelines

The total duration of the subjects' participation in the study will be approximately 7 months. It is anticipated that to enroll all study subjects it will take approximately 3-6 months. The estimated date for completion of this study is 10-13 months after the start of recruitment.

Visit 1: The total time commitment required is approximately 90 minutes once informed consent has been commenced. May be split into two visits if lenses require treatment with Hydra-PEG.

Visit 2: The total time commitment required is approximately 30 minutes.

Visit 3: The total time commitment required is approximately 30 minutes.

Visit 4: The total time commitment required is approximately 30 minutes.

Visit 5: The total time commitment required is approximately 30 minutes.

9.0 Study Endpoints

The primary endpoints in this study are as follows:

- visual acuity
- contact lens comfort questionnaire (OSDI, additional subjective questions)
- ocular surface staining
- tear break-up time

The secondary endpoints in this study are as follow:

- contact lens fitting characteristics (apical clearance, limbal clearance, scleral landing evaluation)
- convenience of Tangible CLEAN & BOOST systems
- satisfaction with CLEAN & BOOST system
- cleaning/conditioning efficacy of CLEAN & BOOST system

10.0 Procedures Involved

Once a subject has been identified, the initial visit will be scheduled. During the initial visit, informed consent will be completed. Prose lenses will be collected and sent for coating (or re-coating) with Hydra-PEG unless the coating is less than 1 month old and the investigator determines the surface is still wetting. All lenses will be coated with the Hydra-PEG coating for this study. If lenses are collected, this will conclude visit 1A. If lenses are not collected, the investigator will proceed to visit 1B tasks. Visit 1B tasks include the following: (1) dispensing Hydra-PEG coated lenses (if collected). (2) an investigator will conduct visual acuity assessments of both eyes (Snellen). (3) An investigator will record the patient's medical history. (4) The subjects will be asked to complete a survey (on contact lens satisfaction and ocular surface symptoms). (5) After the survey, tear break-up time will be measured. Then, slit lamp assessment of the lenses, and then of the cornea and conjunctiva (after lens removal) with and without sodium fluorescein staining will be performed. After this visit, the subjects will then wear the lenses for 30 days, on a daily basis as they habitually would, cleaning the lenses with Tangible CLEAN. Subjects with a sensitivity to multipurpose solutions may alternatively use ClearCare for daily lens treatment. Two days after the completion of visit 1, the study coordinator will conduct a phone survey regarding lens comfort. After 30 days of lens wear, they will report for visit 2.

At the second visit, the same testing will be performed from visit 1, the subject will also complete the surveys listed in Table 1, and then the Tangible Boost kit or the placebo kit (consisting of two vials with saline) solutions will be dispensed (randomized by Sponsor prior to shipment to BostonSight). Subjects will be trained on the use of Tangible Boost, and the subjects will be asked to store their lenses in the given solution for 30 minutes that evening, and then transfer their lenses to Tangible CLEAN multipurpose rigid lens solution for overnight storage.

The clinician will review these instructions with the patient. The instructions are also included on the Boost packaging and in the instructional leaflet.

The subjects will report 2-9 days later for visit 3, at which time the comfort and visit tests and surveys will occur again. After visit 3, the subjects will continue to wear the study lenses daily for an additional 5 months, treating their lenses again in the Boost or placebo solution at the every 30 days, otherwise cleaning nightly with Tangible CLEAN, and will then report to the clinic again 30 days after the second treatment (approximately 90 days after the initial Hydra-PEG lens dispense). The same visit testing will be done at the fourth visit, and the surveys will be completed. The final visit will take place approximately 180 days after lens dispense, and will include the same visit testing and surveys. At this time the study will conclude. Throughout the study, the research coordinator will call patients to remind them to perform the Boost treatments on the appropriate days. The reminder calls for the third and sixth Boost treatments will also include a short verbal survey.

The following table outlines each of the study visits and tells what procedures will be done at each visit:

Procedure	Length of Time Required for	Frequency of Repetition
VISIT 1: Initial Evaluation		
Part A		
Informed consent & HIPAA	30-40 minutes	Once
General History and medications	5-10 minutes	Once
Collection of lenses for Hydra-PEG coating (if necessary)	5 minutes	Once
Part B		
Dispense lenses (if collected)	5 minutes	Once
Visual Acuity	5 minutes	Once per visit
Questionnaires (OSDI + V1 questions)	10 minutes	Once per visit
Slit-lamp Examination (with lenses on and after lens removal)	10 minutes	Once per visit
Review lens care instructions	5 minutes	Once
TOTAL TIME	60-90 minutes	
VISIT 2: Boost Dispense		
Visual Acuity	5 minutes	Once per visit
Questionnaires (OSDI + V2 questions)	10 minutes	Once per visit
Slit-lamp Examination	10 minutes	Once per visit

Boost dispense and instructions	5 minutes	As needed
TOTAL TIME	30 minutes	
VISIT 3: Tangible Boost Initial Evaluation		
Visual Acuity	5 minutes	Once per visit
Questionnaires (OSDI + V3 questions)	10 minutes	Once per visit
Slit-lamp Examination	10-20 minutes	Once per visit
TOTAL TIME	25-35 minutes	
VISIT 4: Tangible Boost Midpoint Assessment		
Visual Acuity	5 minutes	Once per visit
Questionnaires (OSDI + V4 questions)	10 minutes	Once per visit
Slit-lamp Examination	10-20 minutes	Once per visit
TOTAL TIME	25-35 minutes	
VISIT 5: Tangible Boost Final Assessment		
Visual Acuity	5 minutes	Once per visit
Questionnaires (OSDI + V5 questions)	10 minutes	Once per visit
Slit-lamp Examination	10-20 minutes	Once per visit
TOTAL TIME	25-35 minutes	

Table 1. Outline of study visits and testing.

The testing descriptions are summarized in the table below:

Test	Description
General History and Medications	Participants will be asked questions about their general, ocular and medication use histories along with contact lens use history if applicable.
Questionnaires	Subjects will be asked to fill out the following questionnaires: <ul style="list-style-type: none"> Ocular Surface Disease Index (OSDI) Secondary subjective questions specific to each visit These questionnaires assess the level of eye and/or contact lens discomfort, and assess the subject perception of their habitual lenses and the coated lenses before and after Boost treatment.

Lens Evaluation	The ordered rigid lenses will be applied to the eye of the subject by the investigator, after which the fit and vision will be evaluated. At this time, if the fit of the lens is adequate, the lenses will be dispensed.
Visual Acuity	The participant's vision in each eye while wearing lenses will be measured with a high contrast visual acuity chart. The participant will be asked to cover one eye and read the chart, and this procedure will be repeated for the other eye.
Slit-lamp Examination	The participant's front portion of each eye and contact lenses will be examined with a lighted microscope. The participant will be asked to place his/her chin on the chinrest and place his/her forehead against the bar and look straight ahead. The instruments light will be shined onto the eye to visualize the ocular surface for approximately 2-3 minutes per eye. Tear break up time will be measured to assess the wettability of the front surface of the lens. Photographs will be taken at the discretion of the investigator.
Sodium Fluorescein	Sodium fluorescein staining will be used to evaluate ocular surface damage indicated by cell damage or death. Corneal staining will be scored using the Oxford grading scale.

Table 2. Descriptions of tests

Statistical Analysis: Each individual will act as their own control to measure differences in pre and post contact lens measurements (paired non-parametric statistics). Data will also be blocked into groups based on patient disease history (SJS, SS, or GVHD vs. dry eye patients). Preliminary data will be analyzed after visit 5, with full analysis performed after all subjects have completed all 6 visits.

The following data will be collected in this study:

- visual acuity
- questionnaires (OSDI, additional subjective questions)
- tear break-up time
- ocular surface staining
- contact lens fitting characteristics (apical clearance, limbal clearance, scleral landing evaluation)

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	Visit 1A/B Day 0	Phone Visit Day 2	Visit 2 Day 30 +/- 7	Visit 3 Day 32 2-9 after V 2	Phone Visit Day 60 30 +/- 7 after V2	Phone Visit Day 90 60 +/- 7 after V2	Visit 4 Day 92 2-9 after TX 3	Phone Visit Day 120 90 +/- 7 after V2	Phone Visit Day 150 120 +/- 10 after V2	Phone Visit Day 180 150 +/- 10 after V2	Visit 5 Day 182 2-9 after TX 6
Consent	X										
Medical History	X										
Enroll	X										
Collect/Dispense Lenses*	X										
Boost dispense			X				X				
Boost Treatment***			X		X	X		X	X	X	
Exam	X		X	X			X				X
Patient questionnaires	X		X	X			X				X
Phone survey		X				X				X	
Treatment reminder				X	X	X		X	X	X	

*Complete lens collect/dispense only if Hydra-PEG treatment required

** Complete visit 1B only if collect/dispense visit required

*** Completed after visit

Table 3. Schedule of Assessments.

11.0 Setting

Subjects will be asked to complete the study visits, which will be conducted in clinical facilities at Boston Sight.

12.0 Drugs or Devices

Scleral lenses are considered class II medical devices by the FDA. All rigid lens materials are FDA approved for use in a rigid contact lens, they are not investigative devices.

The Tangible Boost Replenishing system is not yet FDA approved but biocompatibility and toxicology testing to support FDA filing has been completed (see Appendix A). A clinical trial was recently completed at the University of Houston College of Optometry to evaluate Boost on subjects without ocular surface disease. No serious adverse event were reported. The Boost system contains the same ingredients as the Hydra-PEG coating that it is designed to replenish.

13.0 Risks to Subjects

This study presents a minimal risk to subjects. Contact lens subject risks are those that are already associated with wearing a contact lens. These risks include developing an abrasion ('cut' on the eye) during lens application or removal, excessive debris accumulation on or beneath the lenses, ocular stinging, redness, itching, or irritation. All contact lens wearers are at risk for

developing inflammatory and/or infectious complications and vision loss during lens wear, but there is no added risk by participating in this study. There are no unforeseeable risks that the investigators can imagine with any of the procedures in this study.

If a subject experiences an adverse event during the duration of the study, they will be instructed to call the study coordinator who will communicate with the investigators to determine the best course of action. If the subject needs to be seen due to an adverse event, a study investigator will examine them and the customary procedure for management will be followed.

The investigators will be instructing subjects on the proper handling and care of their lenses, and will instruct the subjects of symptoms of an adverse event and who to call in that case (the coordinator). If an adverse event such as an abrasion occurs during a study visit, the condition will be treated as it is customarily, and the fees associated with treatment will be covered by the study.

Hydra-PEG lenses treated with the Tangible Boost solution are identical to lenses coated with Hydra-PEG by the manufacturer. To address concerns of improper use of the Hydra-PEG/Boost solution by patients, we have also performed cytotoxicity and ocular irritation testing on the solution itself, and determined that the solution is non-cytotoxic and is not an ocular irritant. For this trial, sterility testing will be performed on each lot of Boost prior to lot release.

14.0 Potential Benefits to Subjects

There may be no benefit to the subject for participation in this study. The potential benefit to subjects includes enhanced lens comfort due to both the Hydra-PEG coating and the use of the Tangible CLEAN/BOOST system.

15.0 Withdrawal of Subjects

Subjects will be withdrawn from the study if they are unable to complete the tasks in the study protocol. In addition, if they experience an adverse event in which the investigator does not feel that the subjects should continue wearing the scleral lenses, they will be withdrawn.

The data from a subject that withdraws or is terminated from the study will not be included in the analysis.

16.0 Costs/Payments to Subjects

The only cost that the subjects may be responsible for in this study is the cost of transportation to and from the appointments.

Participants will receive a \$100 Amazon gift card upon completion of all of the study visits.

17.0 Compensation for Research-Related Injury

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If there is an ocular injury in this study directly related to the use of the contact lenses and the cleaning systems, treatment for the injury and any subsequent referrals will be covered by the study. The subject will not receive any direct compensation. If there is an unrelated or non-ocular injury during a subject's enrollment in the study, it will not be covered by the study.

18.0 Confidentiality

The subject ID worksheet, informed consent, subject surveys, and examiner worksheets will all be kept in a single binder, locked in the office of the principal investigator. The informed consent forms and the subject ID worksheet will be kept in a separate binder from the study data.

At the start of participation in the study, the subject will be assigned a non-identifiable subject ID that will be used for identification on all other documents used in the study. This identification document, which will be the only document that decodes the subject, will be kept in a locked filing bin in a locked room within BostonSight, separate from the informed consent and other study documents. Names, email addresses, and telephone numbers will be recorded in this subject ID worksheet, which will be a paper file kept in the locked office of the principal investigator.

All other exam findings (survey, questionnaire, exam findings) will be recorded on the paper forms and stored in a binder. This binder will be kept locked in the principal investigator's office when not being used to add or remove data collection worksheets.

Only the investigators will have access to the paper and electronic records kept in this study.

All study data will be stored for a minimum of 3 years following study completion. The link will be maintained to allow pertinent regulatory or government agencies to inspect the data and ensure that subjects participated in the study. The principal investigator will be responsible for maintaining study data security and subject confidentiality.

19.0 Provisions to Protect the Privacy Interests of Subjects

We will ensure that all data is maintained with confidentiality and will assure subjects of this when they begin the study. If subjects are not comfortable with disclosing any of the information that is asked in the study, they will not be pressured to disclose, but they may not be able to participate if the withholding prevents us from screening or determining eligibility in the study. All PHI (DOB, name, health information) will be stored in the locked office of the Principal Investigator.

Subjects will only be asked questions that are relevant to the study and their ocular health. The investigators, who are all optometrists that regularly see patients and communicate about potentially sensitive information, have been trained to develop proper rapport with patients and study subjects. All investigators will make every effort to avoid seeming intrusive when asking the subjects questions.

20.0 Informed Consent Process

Informed consent will be obtained before any testing is done. The subject will be provided an informed consent document written in non-technical language. The study staff will review the document with the subject and will give the subject adequate time to review the form and ask any questions before deciding whether to participate. After answering any questions, if the study staff believes the subject comprehends the elements of the informed consent document, the study staff will invite the subject to participate in the study and will have the subject sign the consent form. The investigators and key personnel associated with the informed consent process are trained to not influence the participant in their decision to participate in the research or not. The individual may choose not to sign the consent form without any coercion from the study personnel. Non-participation in the study from patients will not impact future care. Informed consent is estimated to take approximately 35 minutes for this study.

21.0 Process to Document Consent in Writing

Participants will complete the Informed Consent document.

22.0 HIPAA

Study will be performed in compliance with HIPAA regulations. A partial waiver is requested for study recruitment. Subjects will be asked to sign a HIPAA Authorization to allow access to their private information.

23.0 Data Management

Data will be stored in a study paper file at Boston Sight. Electronic data will be stored on a password-protected computer in a locked office. All study data will remain at Boston Sight for a minimum of 3 years following study completion. The principal investigator will be responsible for maintaining study data security and subject confidentiality, and the PI and the study coordinator will be responsible for receipt and transmission of the data. The investigative team, study sponsor and inspectors from regulatory agencies such as the US Food and Drug Administration will have access to the data if requested for study monitoring or an audit.

All collected data will be documented on study documents and analyzed for differences between baseline and test data. Hypothesis testing will be performed using statistical analyses including parametric or nonparametric comparisons (i.e., t-tests, signed-rank tests), analysis of variance, general linear models, correlation, or regression techniques.

24.0 Specimen Use and Banking – N/A

25.0 Sharing of Results with Subjects

Study results will not be shared with subjects, unless the investigator feels that the subject should know something about the ocular health of their eye as a result of the study.

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26.0 Resources

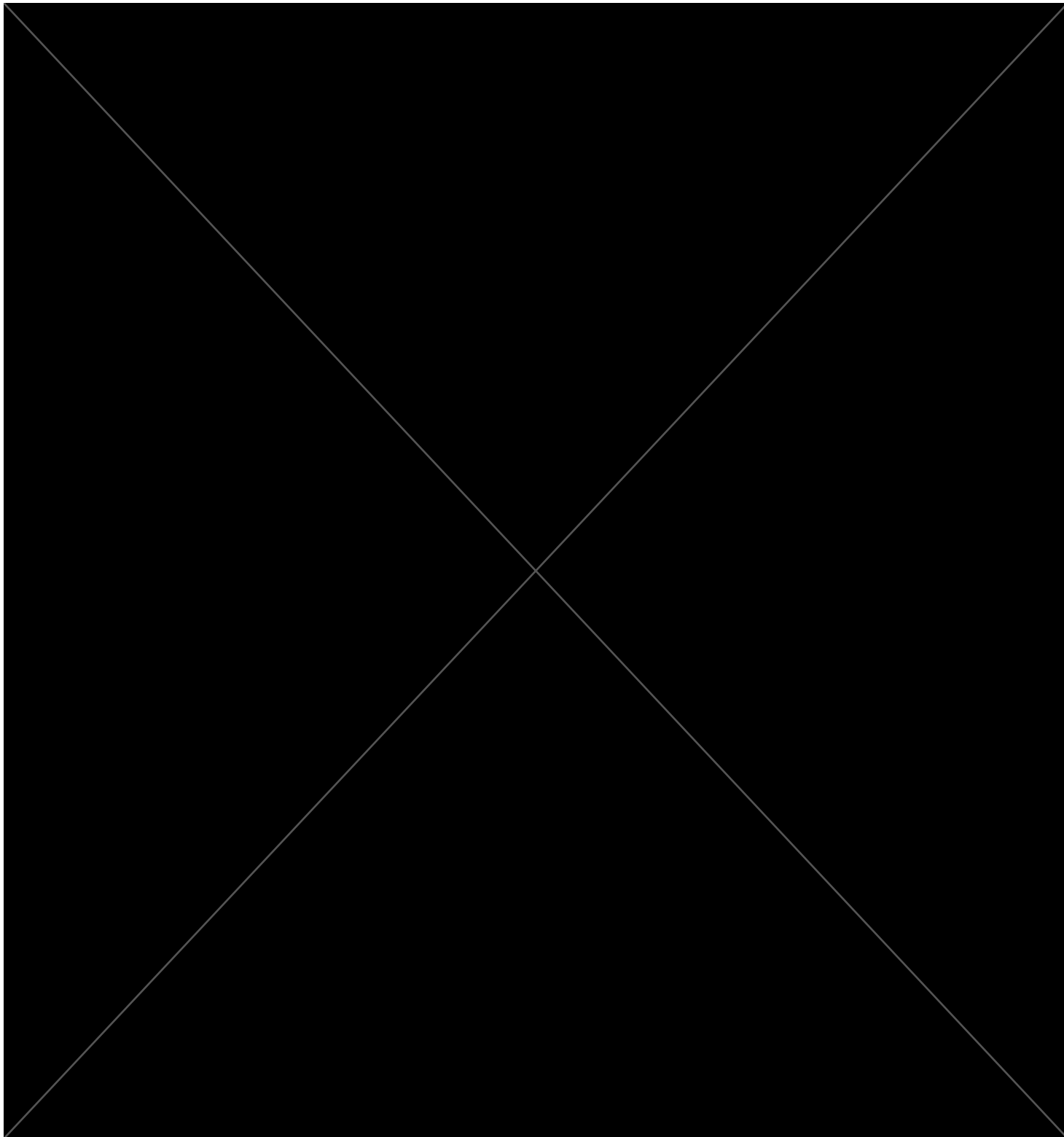
All investigators in this study are optometrists, and are qualified to examine subjects and evaluate the performance of the contact lenses. The investigators all have experience working within Boston Sight, and with all the exam rooms, equipment, and data storage rooms. All investigators have completed the necessary training for good clinical practices, and are specialists in lens fitting and management. The study coordinator is an experienced coordinator who is also trained on IRB practices and is experienced with informed consent processes and confidentiality.

We do not expect to have difficulty recruiting subjects in this study. Most of our subjects will come from current patients of Boston Sight.

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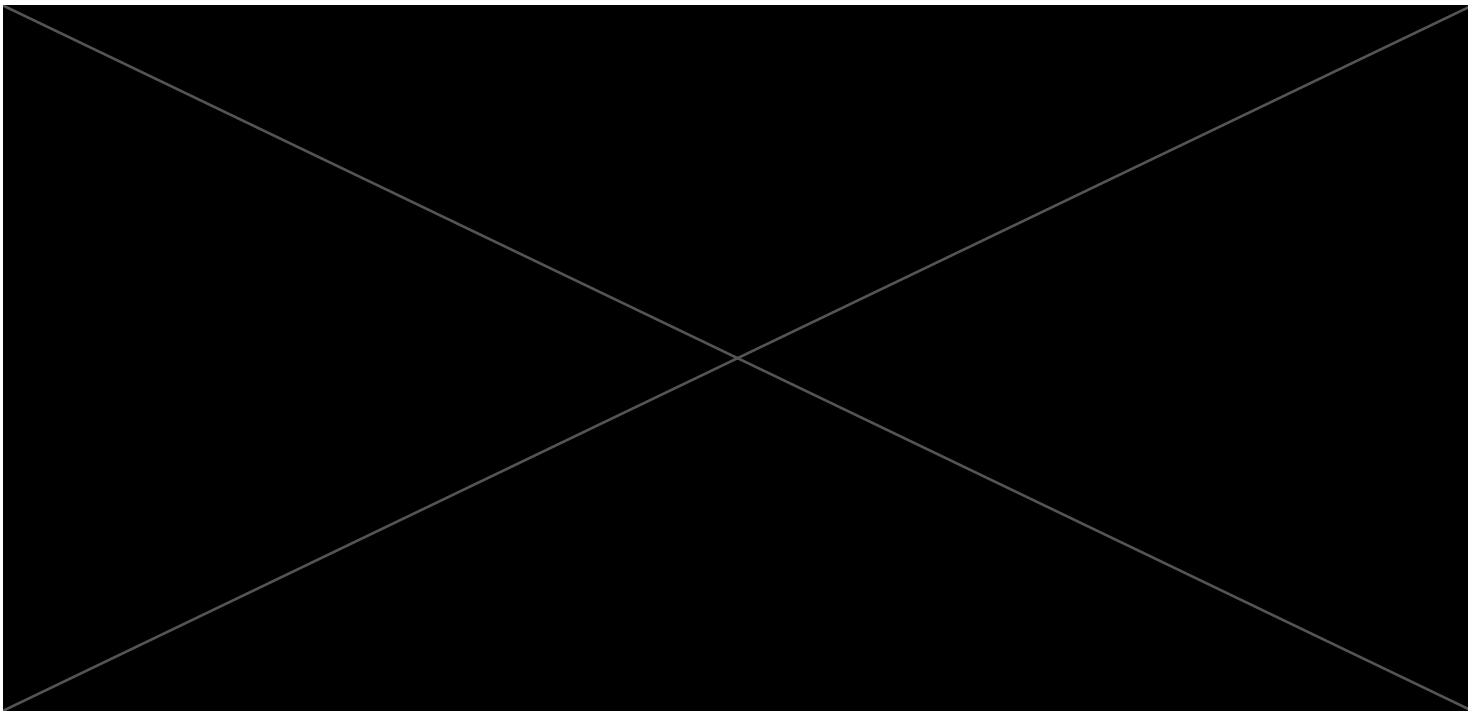
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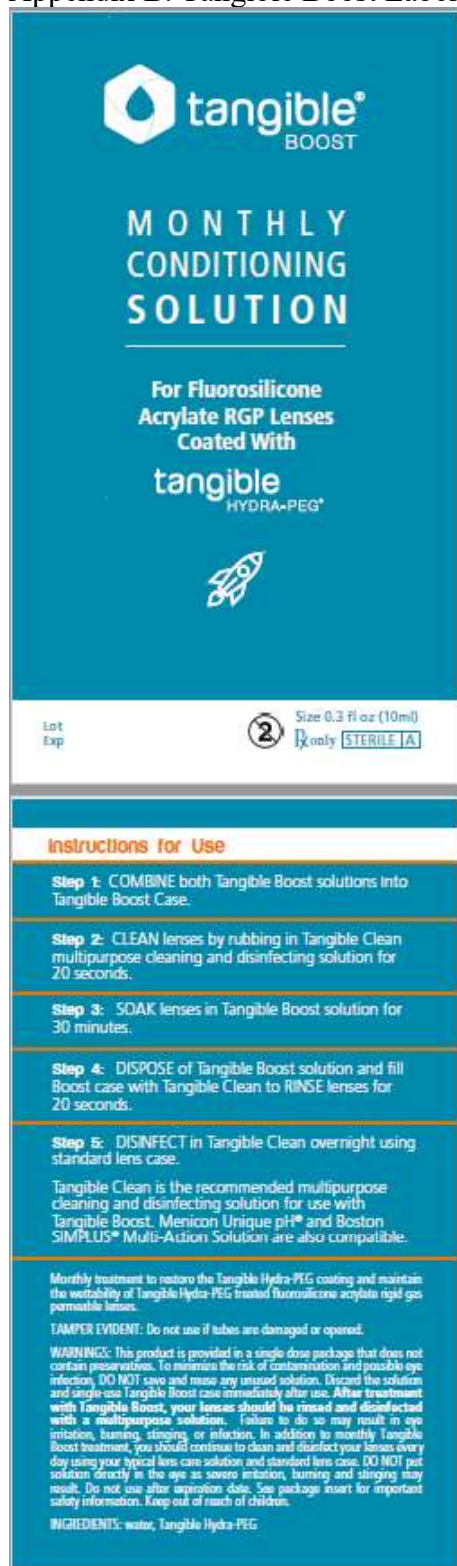
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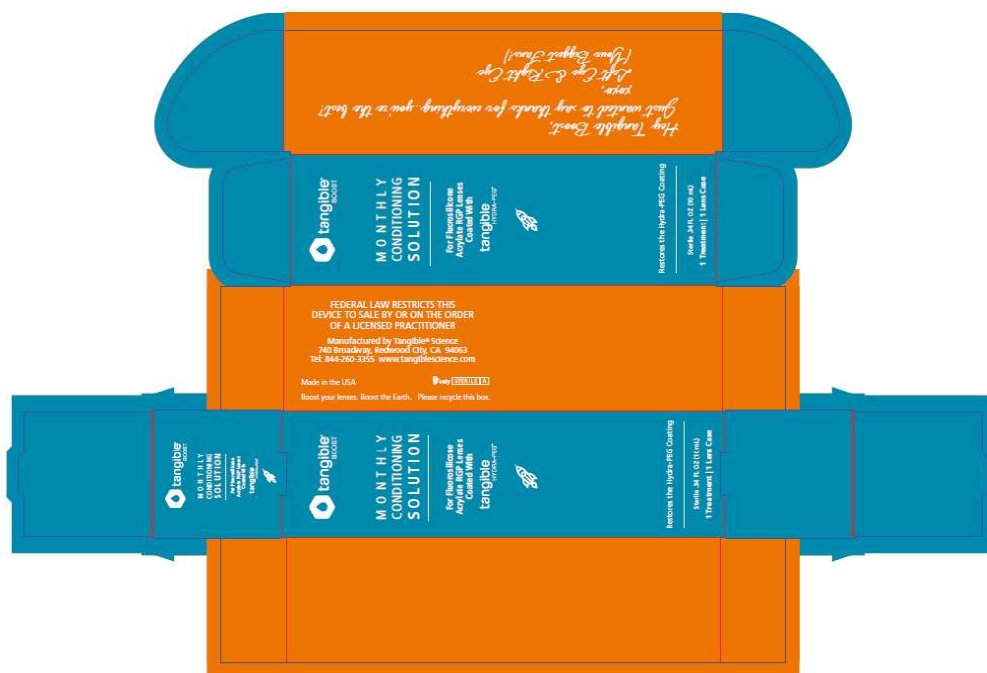
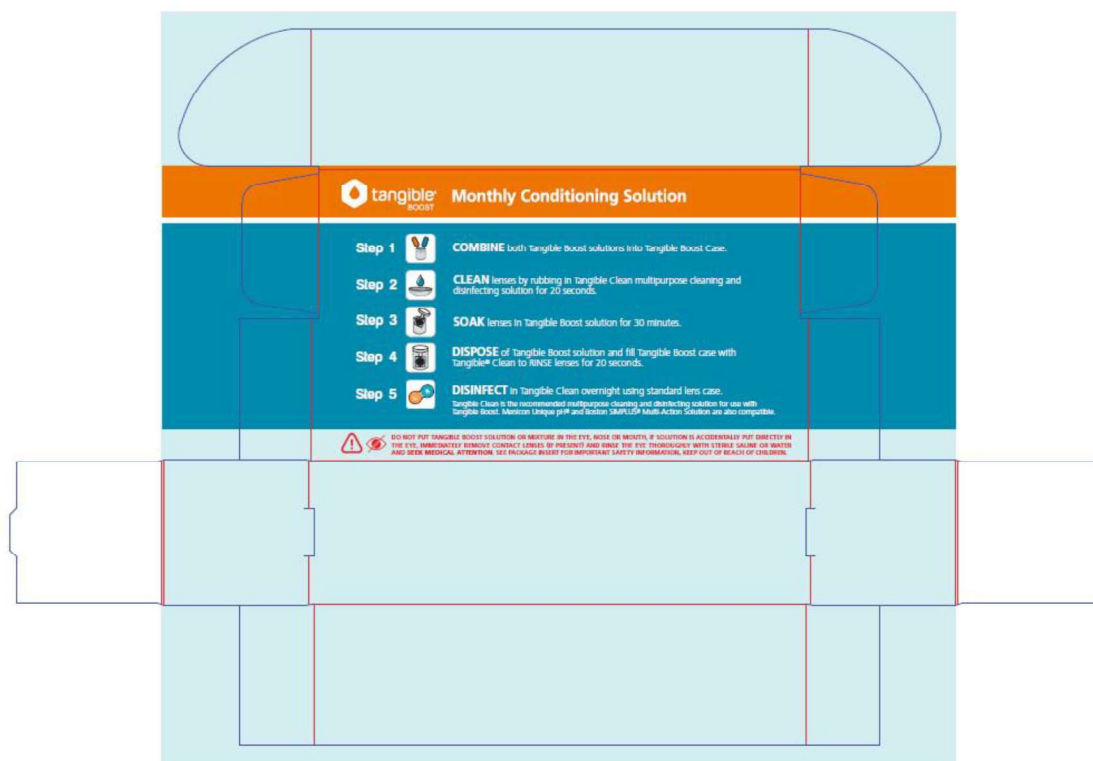
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Appendix B. Tangible Boost Labeling



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Monthly Conditioning Solution



Instructions for Use

MONTHLY TREATMENT TO RESTORE THE TANGIBLE® HYDRA-PEG® COATING AND MAINTAIN THE WETTABILITY OF TANGIBLE HYDRA-PEG TREATED FLUOROSILICONE ACRYLATE RIGID GAS PERMEABLE LENSES

STEP 1



COMBINE both Tangible Boost solutions into Tangible Boost Case.

STEP 2



CLEAN lenses by rubbing in Tangible Clean multipurpose cleaning and disinfecting solution for 20 seconds.

STEP 3



SOAK lenses in Tangible Boost solution for 30 minutes.

STEP 4



DISPOSE of Tangible Boost solution and fill Tangible Boost case with Tangible Clean to RINSE lenses for 20 seconds.

STEP 5



DISINFECT in Tangible Clean overnight using standard lens case. Tangible Clean is the recommended multipurpose cleaning and disinfecting solution for use with Tangible Boost. Menicon Unique pH® and Boston SIMPLUS® Multi-Action Solution are also compatible.



DO NOT PUT TANGIBLE BOOST COMPONENTS OR MIXTURE IN THE EYE, NOSE OR MOUTH. IF SOLUTION IS ACCIDENTALLY PUT DIRECTLY IN THE EYE, IMMEDIATELY REMOVE CONTACT LENSES (IF PRESENT) AND RINSE THE EYE THOROUGHLY WITH STERILE SALINE OR WATER. SEEK MEDICAL ATTENTION. KEEP OUT OF REACH OF CHILDREN.

INSTRUCTIONS FOR USE
PLEASE READ CAREFULLY AND KEEP THIS PACKAGE INSERT FOR FUTURE USE.

DESCRIPTION: Two sterile, preservative-free, unit-dose solutions to be combined in the Tangible Boost lens case. Solutions contain water, and Tangible Hydra-PEG. Federal law restricts this device to sale by or on the order of a licensed practitioner.

ACTIONS: Monthly treatment with Tangible Boost restores the Tangible Hydra-PEG coating and maintains the wettability of Tangible Hydra-PEG treated fluorosilicone acrylate lenses.

INDICATIONS: Monthly treatment to restore the Tangible Hydra-PEG coating and maintain the wettability of Tangible Hydra-PEG treated fluorosilicone acrylate rigid gas permeable lenses.

CONTRAINDICATIONS: If you are allergic to any ingredient in this product, **DO NOT USE**. Do not use abrasive or alcohol-based cleaners with Tangible Hydra-PEG treated lenses.

WARNINGS: This product is provided in a single dose package that does not contain preservatives. To minimize the risk of contamination and possible eye infection, **DO NOT** save and reuse any unused solution. Discard the package immediately after use. After treatment with Tangible Boost, your lenses should be cleaned with a multipurpose solution. Failure to do so may result in eye irritation, burning, stinging, or infection. In addition to monthly Tangible Boost treatment, you should continue to clean and disinfect your lenses every day using your typical lens care solution and standard lens case. Discard the solution and single-use Tangible Boost case immediately after use. **DO NOT** put solution directly in the eye as severe irritation, burning and stinging may result. **DO NOT** use after the expiration date.

THIS PRODUCT IS NOT FOR USE WITH ALL CONTACT LENSES. IF YOU ARE NOT SURE OF YOUR CONTACT LENS MATERIAL, PLEASE CONTACT YOUR HEALTH CARE PROVIDER PRIOR TO USE. DO NOT PUT TANGIBLE BOOST COMPONENTS OR MIXTURE IN THE EYE, NOSE OR MOUTH. IF SOLUTION IS ACCIDENTALLY PUT DIRECTLY IN THE EYE, IMMEDIATELY REMOVE CONTACT LENSES (IF PRESENT) AND RINSE THE EYE THOROUGHLY WITH STERILE SALINE OR WATER. SEEK MEDICAL ATTENTION. DO NOT TAKE TANGIBLE BOOST COMPONENTS OR MIXTURE INTERNALLY. DO NOT ALLOW SKIN CONTACT.

SPECIAL STORAGE CONDITIONS: Use before the expiration date marked on the tube and packaging. Keep out of the reach of children. Store at room temperature.

SPECIFIC PRECAUTIONS:

- Lenses should never be placed directly in the eyes from the Tangible Boost solution. Always rinse and disinfect lenses after cleaning.
- If Tangible Boost solution is accidentally put into the eye, immediately remove contact lenses (if being worn) and rinse the eye thoroughly with sterile saline or water. Seek medical attention.
- Use only freshly prepared Tangible Boost solution. Do not reuse Tangible Boost solution or case.
- FOR USE WITH FLUOROSILICONE ACRYLATE RIGID GAS PERMEABLE CONTACT LENSES WITH TANGIBLE HYDRA-PEG. DO NOT USE WITH SILICONE ACRYLATE RIGID GAS PERMEABLE CONTACT LENSES, SOFT CONTACT LENSES INCLUDING HYDROGEL, SILICONE HYDROGEL OR HYBRID CONTACT LENSES.**
- Use only the Tangible Boost barrel lens case for mixing components. Do not use any other container for solution mixing the Tangible Boost solution components.

TITLE: An Evaluation of Tangible Boost Replenishing System for Patients with Stevens Johnson Syndrome, Sjögren's Syndrome, and Graft Versus Host Disease
PROTOCOL NUMBER: DOC-55 (previously STM-0856 rev A) DATE: 01-03-2020

ADVERSE REACTIONS (Problems and what to do): The following problems may occur: eyes sting, burn or itch (irritation), comfort is less than when lens was first placed on the eye, feeling of something in the eye (foreign body, scratched area), excessive watering (tearing) of the eye, unusual eye secretions, redness of the eye, reduced sharpness of vision (poor visual acuity), blurred vision, rainbows or halos around objects, sensitivity to light (photophobia), dry eyes, serious conditions such as an allergic reaction to a component in Tangible Boost, or an infection.

If you notice any of the above: **IMMEDIATELY REMOVE YOUR LENSES.**

- If the discomfort or problem stops, then look closely at the lens.
- If the lens is in any way damaged, **DO NOT** put the lens back on your eye. Place the lens in the storage case and contact your eye care practitioner.
- If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, thoroughly clean, rinse and disinfect the lens, then reinsert it.
- If the problem continues, **IMMEDIATELY** remove the lens and consult your eye care practitioner.

If any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. Seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage. All adverse reactions observed while using Tangible Boost should be reported to:

Tangible Science
740 Broadway
Redwood City, CA 94063
844-260-3355

DIRECTIONS FOR USE:

General Instructions:

Always wash and rinse your hands before handling your lenses. This will help to prevent eye infections by removing dirt and oils that could get on the lenses. Use only the solutions recommended by your eye care practitioner. Seek advice from your eye care practitioner before making any changes to your care regimen to ensure compatibility with lenses. Always follow the directions for use in the labeling included with each solution, as instructions may be different for each solution. Tangible Boost was designed as a monthly treatment, but patients may experience different rates of coating wear. Follow the instructions of your eye care provider regarding the frequency of Tangible Boost treatment.

SPECIFIC INSTRUCTIONS:

Step 1: **COMBINE** both Tangible Boost solutions into Tangible Boost Case.

Step 2: **CLEAN** lenses by rubbing in Tangible Clean multipurpose cleaning and disinfecting solution for 20 seconds.

Step 3: **SOAK** lenses in Tangible Boost solution for 30 minutes.

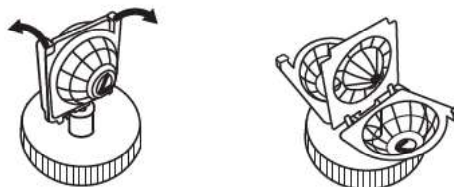
Step 4: **DISPOSE** of Tangible Boost solution and fill Tangible Boost case with Tangible Clean to **RINSE** lenses for 20 seconds.

Step 5: **DISINFECT** in Tangible Clean overnight using standard lens case. Tangible Clean is the recommended multipurpose cleaning and disinfecting solution for use with Tangible Boost. Menicon Unique pH[®] and Boston SIMPLUS[®] Multi-Action Solution are also compatible.

HOW SUPPLIED: Tangible Boost is supplied as two 5 mL components to be combined in the Tangible Boost Case at the time of treatment.

TANGIBLE BOOST CASE INSTRUCTIONS:

Open the lens cages on the Tangible Boost case by pulling on the tabs.



GENERAL LENS CARE PRECAUTIONS:

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.

It is essential that the patient follows the directions of the eye care practitioner and all labeling instructions for proper use of contact lenses and lens care products, including the lens case.

- When disinfecting lenses after Tangible Boost treatment, do not reuse or "top off" old solution left in your lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. "Topping-Off" is the addition of fresh solution to solution that has been sitting in your case.
- Do not store your lenses or rinse your lens case with water or any non-sterile solution. Only use fresh multi-purpose solution (or sterile saline solution) so you do not contaminate your lenses or lens case.

WATER ACTIVITY INSTRUCTION FOR USE: You should not expose your contact lenses to water while you are wearing them.

LENS CASE PRECAUTIONS:

- Replace the lens storage and disinfection case at least once every 3 months or as recommended by the lens case manufacturer or eye care practitioner. (Tangible Boost case is single-use only)
- Clean and disinfect your lens case every day because contact lenses can be a source of microbial growth and cause serious eye infections.
- Never use water to rinse or clean your case.
- Never leave residual contact lens solutions in your case.
- Empty and clean your contact lens case with digital rubbing (rubbing with your clean finger tips) using fresh, sterile disinfecting solutions/contact lens cleaner after each use. Never use water. Rinse the case with fresh, sterile disinfecting solutions (never use water). Wipe the lens case dry with fresh, clean, lint-free tissue. If you are air-drying your case be sure that no residual solution remains in the case before allowing it to air dry. Never recap the lens case lids after use unless additional cleaning methods have been performed.

WARNING: Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If the contact lenses have been exposed to water such as when showering, swimming in pools, lakes, or oceans, you should discard them and replace them with a new pair. You should ask your eye care professional for recommendations about wearing your lenses during any activity involving water.

R_x Only

STERILE	A
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MANUFACTURED FOR:

Tangible Science, 740 Broadway, Redwood City, CA 94063, 844-260-3355

TITLE: An Evaluation of Tangible Boost Replenishing System for Patients with Stevens Johnson Syndrome, Sjögren's Syndrome, and Graft Versus Host Disease

PROTOCOL NUMBER: DOC-55 (previously STM-0856 rev A)

DATE: 01-03-2020

Appendix C. Investigator Data Collection Sheets

An Evaluation of Tangible Boost Replenishing System for Patients with Stevens Johnson Syndrome, Sjögren's Syndrome, and Graft Versus Host Disease

Subject: _____

Date: ____/____/____

VISIT 1

1. **Time of Day** (military time) : ____:____
2. **Signed informed consent & HIPPA:** ☐ Yes ☐ No
3. **Ethnicity**
☐ Hispanic or Latino ☐ Not Hispanic or Latino
4. **Race**
☐ American Indian or Alaskan Native
☐ Asian
☐ Black or African American
☐ Native Hawaiian or Other Pacific Islander
☐ White
☐ Other, specify _____
5. **Birthdate (mm/dd/yy):** ____/____/____
6. **Gender:** ☐ Male ☐ Female
7. **Lens Indication:** _____
8. **Duration of lens wear (months/years):** _____
9. **Average # hours lens wear per week:** _____
10. **Hours of lens wear today:** _____
11. **OSDI**
OSDI completed and verified: ☐ Yes ☐ No OSDI score: _____
12. **Patient survey**
Patient survey completed and verified: ☐ Yes ☐ No

Examiner Initials: _____

An Evaluation of Tangible Boost Replenishing System for Patients with Stevens Johnson Syndrome, Sjögren's Syndrome, and Graft Versus Host Disease

Subject: _____

Date: ____/____/____

13. Medications

Medication	Dose	Route	Dates of use	Reason
		☐ po ☐ SC ☐ IM ☐ IV ☐ topical ☐ other _____	____/____/____ to ____/____/____ ☐ current	☐ Dx Med Condition ☐ Acute Condition ☐ Prophylaxis ☐ Supplement ☐ other: _____
		☐ po ☐ SC ☐ IM ☐ IV ☐ topical ☐ other _____	____/____/____ to ____/____/____ ☐ current	☐ Dx Med Condition ☐ Acute Condition ☐ Prophylaxis ☐ Supplement ☐ other: _____
		☐ po ☐ SC ☐ IM ☐ IV ☐ topical ☐ other _____	____/____/____ to ____/____/____ ☐ current	☐ Dx Med Condition ☐ Acute Condition ☐ Prophylaxis ☐ Supplement ☐ other: _____
		☐ po ☐ SC ☐ IM ☐ IV ☐ topical ☐ other _____	____/____/____ to ____/____/____ ☐ current	☐ Dx Med Condition ☐ Acute Condition ☐ Prophylaxis ☐ Supplement ☐ other: _____

14. Medical History

Medical or Ocular Condition	Date of diagnosis	Current tx (check all that apply)	State of Condition
	____/____/____ to ____/____/____ ☐ currently being tx	☐ Medication ☐ Diet/Exercise ☐ Monitor ☐ Therapy (PT, OT, psych) ☐ surgery/chemo ☐ behavioral change ☐ Impending Dx ☐ other: _____	☐ controlled and stable ☐ currently working with doctor for improvement ☐ trying new medication ☐ impending sx/chemo

Examiner Initials: _____

An Evaluation of Tangible Boost Replenishing System for Patients with Stevens Johnson Syndrome, Sjögren's Syndrome, and Graft Versus Host Disease

Subject: _____

Date: ____/____/____

	____/____/____ to ____/____/____ ☐ currently being tx	☐ Medication ☐ Diet/Exercise ☐ Monitor ☐ Therapy (PT, OT, psych) ☐ surgery/chemo ☐ behavioral change ☐ Impending Dx ☐ other: _____	☐ controlled and stable ☐ currently working with doctor for improvement ☐ trying new medication ☐ impending sx/chemo
	____/____/____ to ____/____/____ ☐ currently being tx	☐ Medication ☐ Diet/Exercise ☐ Monitor ☐ Therapy (PT, OT, psych) ☐ surgery/chemo ☐ behavioral change ☐ Impending Dx ☐ other: _____	☐ controlled and stable ☐ currently working with doctor for improvement ☐ trying new medication ☐ impending sx/chemo

History of ocular surgeries, ocular injections or laser procedures?

☐ Yes ☐ No

Type of ocular surgery and when it occurred? _____ Date: ____/____/____

15. Contact lens history

a. Current lens description

b. OD _____
OS _____

16. Visual Acuity with lenses (logMAR): Record # of letters seen and logMAR

OD: _____, _____

OS: _____, _____

17. Slit Lamp Evaluation of Lenses

OD		OS
	Movement	
	Centration	
	Apical Clearance	
	Limbal Clearance	
	Scleral Landing Zone	

Examiner Initials: _____

An Evaluation of Tangible Boost Replenishing System for Patients with Stevens Johnson Syndrome, Sjögren's Syndrome, and Graft Versus Host Disease

Subject: _____

Date: ____/____/____

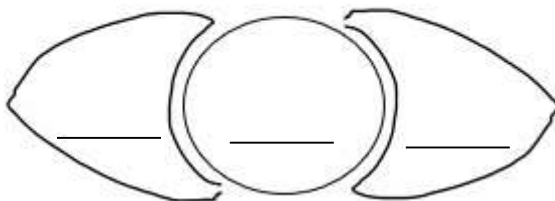
	Tear Break-up Time	
	Comments	

18. Slit lamp exam (after lens removal)

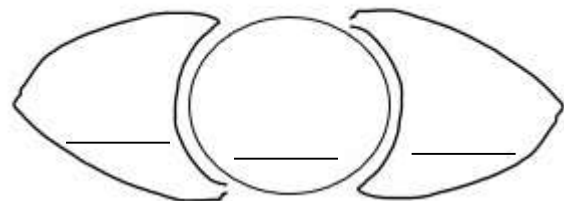
OD			OS	
Notes	Efron grade (0-4)		Efron grade (0-4)	Notes
		Limbal redness		
		Conjunctival redness		
		Papillary conjunctivitis		
		Blepharitis		
		Meibomian gland dysfunction		
		Corneal ulcers		
		Corneal neovascularization		

19. Corneal Fluorescein Staining:

(Oxford Scale for each quadrant: 0-4 grading in each section, total score range 0-12)



OD



OS

TOTAL Score: OD ____ OS ____

20. Administrative

Appointment 2 scheduled?

☐ Yes

☐ No

Examiner initials: _____

An Evaluation of Tangible Boost Replenishing System for Patients with Stevens Johnson Syndrome, Sjögren's Syndrome, and Graft Versus Host Disease

Subject: _____

Date: ____/____/____

VISIT 2

1. Time of Day (military time) : ____:____

2. Hours of lens wear today: _____

3. Currently wearing study lenses? ☐ Yes ☐ No

4. Current Cleaning solution: _____

5. OSDI
OSDI completed and verified: ☐ Yes ☐ No OSDI score: _____

6. Patient survey
Patient survey completed and verified: ☐ Yes ☐ No

7. Medications
a. Any change in medications? ☐ Yes ☐ No
b. If yes, please specify: _____

8. Visual Acuity with lenses (logMAR): Record # of letters seen and logMAR

OD: _____, _____

OS: _____, _____

9. Slit Lamp Evaluation of Lenses with Tangible Hydra-PEG

OD		OS
	Movement	
	Centration	
	Apical Clearance	
	Limbal Clearance	
	Scleral Landing Zone	
	Tear Break-up Time	
	Comments	

Examiner initials: _____

An Evaluation of Tangible Boost Replenishing System for Patients with Stevens Johnson Syndrome, Sjögren's Syndrome, and Graft Versus Host Disease

Subject: _____

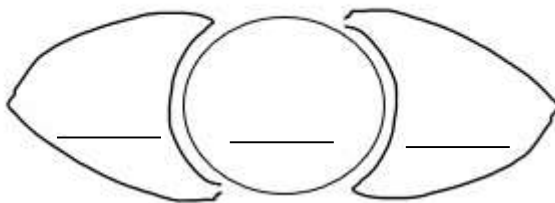
Date: ____/____/____

10. Slit lamp exam (after lens removal)

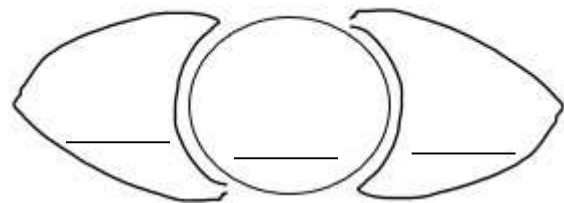
OD			OS	
Notes	Efron grade (0-4)		Efron grade (0-4)	Notes
		Limbal redness		
		Conjunctival redness		
		Papillary conjunctivitis		
		Blepharitis		
		Meibomian gland dysfunction		
		Corneal ulcers		
		Corneal neovascularization		

11. Corneal Fluorescein Staining:

(Oxford Scale for each quadrant: 0-4 grading in each section, total score range 0-12)



OD



OS

TOTAL Score: OD ____ OS ____

12. Administrative

Appointment 3 scheduled?

☐ Yes

☐ No

Examiner initials: _____

An Evaluation of Tangible Boost Replenishing System for Patients with Stevens Johnson Syndrome, Sjögren's Syndrome, and Graft Versus Host Disease

Subject: _____

Date: ____/____/____

VISIT 3

1. **Time of Day** (military time) : ____:____

2. **Hours of lens wear today:** _____

3. **Currently wearing study lenses?** ☐ Yes ☐ No

4. **Current Cleaning solution:** _____

5. **OSDI**
OSDI completed and verified: ☐ Yes ☐ No OSDI score: _____

6. **Patient survey**
Patient survey completed and verified: ☐ Yes ☐ No

7. **Medications**
 a. Any change in medications? ☐ Yes ☐ No
 b. If yes, please specify: _____

8. **Visual Acuity with lenses (logMAR): Record # of letters seen and logMAR**

OD: _____, _____

OS: _____, _____

9. **Slit Lamp Evaluation of Lenses with Tangible Hydra-PEG**

OD		OS
	Movement	
	Centration	
	Apical Clearance	
	Limbal Clearance	
	Scleral Landing Zone	
	Tear Break-up Time	
	Comments	

Examiner initials: _____

An Evaluation of Tangible Boost Replenishing System for Patients with Stevens Johnson Syndrome, Sjögren's Syndrome, and Graft Versus Host Disease

Subject: _____

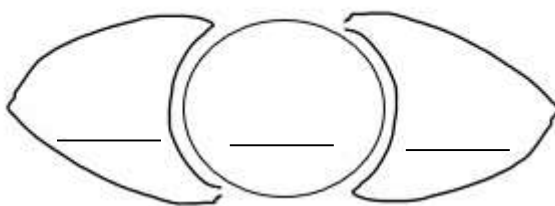
Date: ____/____/____

10. Slit lamp exam (after lens removal)

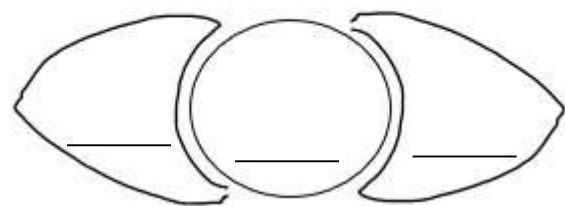
OD			OS	
Notes	Efron grade (0-4)		Efron grade (0-4)	Notes
		Limbal redness		
		Conjunctival redness		
		Papillary conjunctivitis		
		Blepharitis		
		Meibomian gland dysfunction		
		Corneal ulcers		
		Corneal neovascularization		

11. Corneal Fluorescein Staining:

(Oxford Scale for each quadrant: 0-4 grading in each section, total score range 0-12)



OD



OS

TOTAL Score: OD ____ OS ____

12. Administrative

Appointment 4 scheduled?

☐ Yes

☐ No

Examiner initials: _____

An Evaluation of Tangible Boost Replenishing System for Patients with Stevens Johnson Syndrome, Sjögren's Syndrome, and Graft Versus Host Disease

Subject: _____

Date: ____/____/____

VISIT 4

1. Time of Day (military time) : ____:____

2. Hours of lens wear today: _____

3. Currently wearing study lenses? ☐ Yes ☐ No

4. Current Cleaning solution: _____

5. Performed Boost treatment twice? ☐ Yes ☐ No

6. OSDI
OSDI completed and verified: ☐ Yes ☐ No OSDI score: _____

7. Patient survey
Patient survey completed and verified: ☐ Yes ☐ No

8. Medications
a. Any change in medications? ☐ Yes ☐ No
b. If yes, please specify: _____

9. Visual Acuity with lenses (logMAR): Record # of letters seen and logMAR

OD: _____, _____

OS: _____, _____

10. Slit Lamp Evaluation of Lenses with Tangible Hydra-PEG

OD		OS
	Movement	
	Centration	
	Apical Clearance	
	Limbal Clearance	
	Scleral Landing Zone	
	Tear Break-up Time	
	Comments	

Examiner initials: _____

An Evaluation of Tangible Boost Replenishing System for Patients with Stevens Johnson Syndrome, Sjögren's Syndrome, and Graft Versus Host Disease

Subject: _____

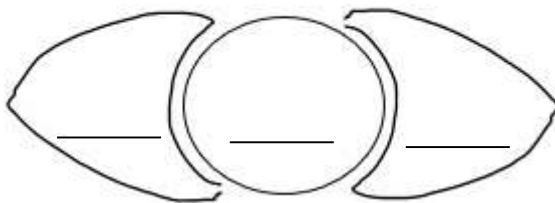
Date: ____/____/____

11. Slit lamp exam (after lens removal)

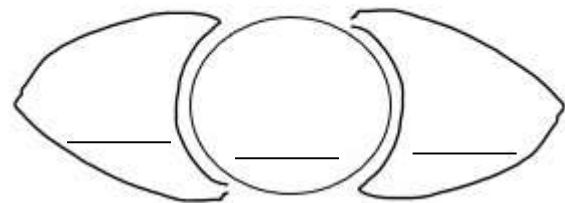
OD			OS	
Notes	Efron grade (0-4)		Efron grade (0-4)	Notes
		Limbal redness		
		Conjunctival redness		
		Papillary conjunctivitis		
		Blepharitis		
		Meibomian gland dysfunction		
		Corneal ulcers		
		Corneal neovascularization		

12. Corneal Fluorescein Staining:

(Oxford Scale for each quadrant: 0-4 grading in each section, total score range 0-12)



OD



OS

TOTAL Score: OD ____ OS ____

13. Administrative

- a. Appointment 5 scheduled? ☐ Yes ☐ No

Examiner initials: _____

An Evaluation of Tangible Boost Replenishing System for Patients with Stevens Johnson Syndrome, Sjögren's Syndrome, and Graft Versus Host Disease

Subject: _____

Date: ____/____/____

VISIT 5

1. Time of Day (military time) : ____:____

2. Hours of lens wear today: _____

3. Currently wearing study lenses? ☐ Yes ☐ No

4. Current Cleaning solution: _____

5. Performed Boost treatment 6 times? ☐ Yes ☐ No

6. OSDI
OSDI completed and verified: ☐ Yes ☐ No OSDI score: _____

7. Patient survey
Patient survey completed and verified: ☐ Yes ☐ No

8. Medications
a. Any change in medications? ☐ Yes ☐ No
b. If yes, please specify: _____

9. Visual Acuity with lenses (logMAR): Record # of letters seen and logMAR

OD: _____, _____

OS: _____, _____

10. Slit Lamp Evaluation of Lenses with Tangible Hydra-PEG

OD		OS
	Movement	
	Centration	
	Apical Clearance	
	Limbal Clearance	
	Scleral Landing Zone	
	Tear Break-up Time	
	Comments	

Examiner initials: _____

An Evaluation of Tangible Boost Replenishing System for Patients with Stevens Johnson Syndrome, Sjögren's Syndrome, and Graft Versus Host Disease

Subject: _____

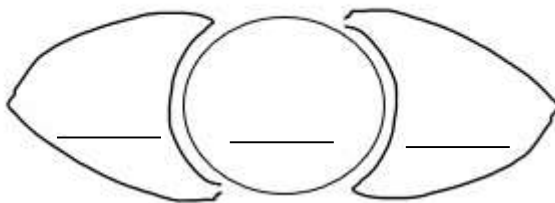
Date: ____/____/____

11. Slit lamp exam (after lens removal)

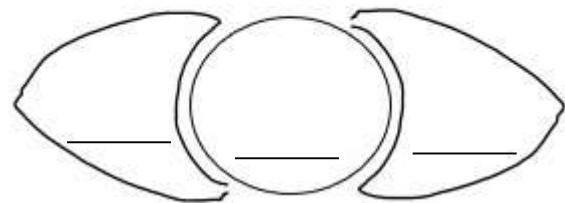
OD			OS	
Notes	Efron grade (0-4)		Efron grade (0-4)	Notes
		Limbal redness		
		Conjunctival redness		
		Papillary conjunctivitis		
		Blepharitis		
		Meibomian gland dysfunction		
		Corneal ulcers		
		Corneal neovascularization		

12. Corneal Fluorescein Staining:

(Oxford Scale for each quadrant: 0-4 grading in each section, total score range 0-12)



OD



OS

TOTAL Score: OD ____ OS ____

Examiner initials: _____