*Instructions:  The purpose of this document is to provide a guide for staff when addressing participants’ questions regarding the Before and After Sex product use instructions. It is strongly recommended that site staff become familiar with the FAQs thus facilitating the counseling process.  Sites may choose to adapt this document and provide directly to participants. If this is done, IRB/EC approval prior to distribution to participants is required. If there are additional questions that should be added to this document, please send them to FHI 360 (*[*mtn017fhi@mtnstopshiv.org*](mailto:mtn017fhi@mtnstopshiv.org)*).*

Q. What if a participant inserts one dose of gel into the rectum expecting to have receptive anal sex within 12 hours but for some reason sex does not happen? What should the participant do?

A. In cases when a dose was inserted expecting sex and sex does not happen, the participant should insert the second dose within 24 hours of the first dose. For example, if a participant inserted a dose at 7:00 p.m. on Friday night expecting sex that night, but sex did not happen, the second dose should be inserted any time before 7:00 p.m. on Saturday.

Q. What if a participant inserts one dose of gel in anticipation of sex but sex does not happen within 12 hours but does occur within 24 hours?

A. In this case, the second dose should be inserted as soon as possible after sex, within the 24 hours following the first dose.

Q. What if a participant forgets to insert the gel before having sex?

A. If a participant forgets to insert the gel before having sex, that dose is considered

missed. The participant should insert a dose WITHIN 12 HOURS after sex.

Q. What if a participant inserts a dose of gel but has a bowel movement before sex occurs. Should Another dose as a pre-dose be inserted again?

A. No, another dose should not be inserted after a bowel movement. A post-dose-sex should be used as soon as possible after sex, within 12 hours.

Q. What if a participant starts to insert a dose of gel but accidently drops the applicator prior to dispensing the entire contents of the pre-filled applicator. Should the participant use another pre-filled applicator of gel to ensure one full dose of gel is used?

A. If most of the study gel is not inserted, and comes out on your outside, dispose of that applicator and use a new applicator to insert another dose of study gel.

Q. What if a participant is currently abstinent, works in the evening and reports he is unable to use the gel in the evening once a week. How should the participant insert his weekly two doses of gel?

A. If the participant is not able to insert the dose in the evening, the dose should be applied before the longest period of rest and the next dose within 12 hours of inserting the first dose. it is important to remember that at a minimum the participant should use 2 doses of product at least once per week at a day and time that is convenient for him/her.

Q. What if a participant inserts a dose of gel in anticipation of sex but sex does not happen within 24 hours and a second dose of gel is not inserted. However, sex does happen the next day without a pre-sex dose inserted. Should the participant insert a post-sex dose as scheduled?

A. Yes, the post-sex dose should be inserted within 12 hours of sex. the pre-sex dose is considered missed.

Q. When should a participant avoid douching?

A. Whenever possible, participants should avoid douching after the insertion of a dose of study gel. If a participant wants to douche in preparation for sex, douching should occur before the insertion of the gel.

Q. What if a participant has sex multiple times over the course of a three day period. Should the participant insert a pre- and post-dose before and after each sex act?

A. No, the participant should insert only two doses (one pre-sex dose and one post-sex dose) within 24 hours. For example, if the participant inserts the dose at 7:00 p.m. on a Friday night and has sex multiple times between Friday night and Saturday, the next dose should be inserted before 7:00 p.m. on Saturday night. after 7:00 P.M. on Saturday night, Another pre-sex dose should be inserted before sex and the next dose should be inserted within 12 HOURS AFTER SEX (AND WITHIN 24 hours of the previous dose). a pre-sex dose always starts a new 24 hour period.

Similarly, if a participant inserts a dose at 10:00 am on a Friday morning, has sex Friday afternoon, inserts the post sex dose, but then has sex again at midnight, no additional doses should be inserted before or after the second sex act at midnight.

Q. What if a participant has not had sex in 6 days, so he/she inserts the dose on the evening of the sixth day as instructed, but then has sex after 12 hours of gel insertion, when should the second dose (after sex) be inserted?

A. The second dose should be inserted as instructed, as soon as possible, after the sex act and within 24 hours of the first dose.

Q. What if a participant notices some gel leakage right after gel insertion, should another dose be inserted?

A. It is POSSIBLE that some study gel will leak out. If this happens, another dose should not be inserted. the Participant should be counseled on proper gel insertion to ensure the applicator is appropriately inserted before pushing the plunger. As a guide, if the participant holds the applicator half way along the barrel and inserts it until his/her fingers touch the anus – it will be correctly inserted.

Q. Could the gel be used as lubricant?

A. No, participants should be counseled that the study gel is not a lubricant; Good Clean Love lubricant is provided as part of the study for participants to use for this purpose. The study gel is an investigational product that is being tested for safety and acceptability for the prevention of HIV.

Q. What if a participant chooses not to use the gel around the time of sex because it is too hard to remember when it should be used?

A. Reinforce the importance of using study gel as instructed (within 12 hours prior to having receptive anal sex and as soon as possible but within 12 hours after having receptive anal sex). Continue to counsel the participant to report any non-use of the study gel according to scheduled regimen to site staff and work with the participant to identify ways to remind the participant of how to appropriately use study gel before and after sex.

Q. What about if the participant does not want to use the gel because every time she/he uses the gel, she/he has really bad gas and/or a bowel movement and it interferes with his/her plans to have sex?

A. Site staff should work with the participant in identifying strategies to minimize adverse events interfering with sex, for example, the participant could use the study gel early in the 12 hours prior to sex in hopes that adverse events of study gel use do not interfere with anal sex.

Q. How long does a participant have to wait after inserting the gel to engage in analingus (rimming)?

A. When using the applicator, study gel is inserted approximately 2-3 inches into the rectum away from the anus so study gel should not interfere with performing oral sex. However, a small amount of study provided lubricant, Good Clean Love, may be present as it is used to aid with insertion of the applicator. The study provided lubricant contains 100% natural and organic ingredients and 100% edible.

Q. Can the gel be used for penile application during RAI regimen?

A. No, the study gel is not intended to be used for penile application. The study gel is a rectal gel that is being tested in the study to evaluate its safety and acceptability and should not be used as a lubricant. Study participants may use the study provided lubricant, Good Clean Love, which may be applied if personal lubrication is desired and good clean love is safe when used with latex condoms.

For general Product use questions, please refer to ssp section Appendix 7-6 (<http://www.mtnstopshiv.org/node/4643>).