

Counselor Reference for Ring Use Education at Enrollment

LEAVE THE RING INSERTED

The ring should be left inserted all day, every day, including during menses, bathing, and sex.

- Previous studies have shown that it is not harmful to leave the ring inserted during any of these activities.
- If you have concerns that the ring has slipped out, you can always use your finger to check that it is still inserted. It is uncommon for the ring to slip out, but this may happen.
- The ring will not block your menstrual flow.
- If you have discomfort, or if your partner tells you he can feel the ring during sexual activity, check the placement of the ring. Wash your hands, and try to gently push the ring further into your vagina. It's impossible for the ring to be pushed too far up or get lost inside the body. Even if you or your partner may be able to feel it, it is safe to leave it inserted during sex.
- If you experience discomfort that cannot be resolved by moving the ring further up in the vagina, contact the clinic as soon as possible.
- If you have difficulties using the ring as directed, it is also important that you share these experiences with site staff. Knowing when women were able to use the ring and when they were not is also very important for knowing whether these products are safe/effective for HIV prevention.

IF THE RING FALLS OR IS TAKEN OUT

**Somewhere clean: Rinse the ring and try to reinsert it as soon as possible.
Somewhere dirty: DO NOT reinsert. Put it in the bag provided and contact the clinic.**

- Do not use soap or hot water to clean the ring; rinse only in clean water which is at room temperature or cool before reinsertion.
- If the ring falls out somewhere that is unsanitary, it is okay not to retrieve the ring. Contact or return to clinic to get a new ring.
- Do not rinse the ring unless it will be reinserted into your vagina

REPLACE

After about 4 weeks the ring should be removed and replaced with a new ring.

- This will typically occur at your scheduled clinic visits.
- If you cannot make it to the clinic for your visit, contact the clinic to be rescheduled and do not remove the ring.
- If you anticipate being away and unable to make a visit, tell study staff in advance and they may be able to provide you with an extra ring.
- If the ring is used for more than 4 weeks (28 days), contact the clinic to get a new ring as soon as possible.
- For participants who receive more than one ring: work with participant to determine when she will need to replace the ring and potential reminder methods.

AVOID

Other than the ring, using any vaginal products and devices (other than male and female condoms) is discouraged.

- This includes lubricants for sex, diaphragms, douching products, items used to dry the vagina, as well as vaginally applied medications. If you cannot avoid these, please let us know so we can keep track of how the ring works in this situation. Use of tampons during menses is permitted.
- The reason all participants are asked not to use products in their vagina is because the ring may work differently when different products are present or vaginal products could irritate the vagina leading to higher risk of infection or vaginal adverse events. This could lead to wrong conclusions from this research.

DO NOT SHARE

Insert only the ring assigned to you and do not share your ring with other women.

- If participants do not use the ring assigned to them, it will make it difficult for researchers to learn if the ring helps prevent HIV infection.
- Women who are not in the study should not use the ring, as they do not have the proper medical care to determine if the ring is safe for them. For example, they do not have regular HIV or pregnancy testing.

STORAGE

Used and dirty rings should be stored in the bag provided to you. If you have been provided with an additional ring, store it in the packaging until needed for use.

- If you do not have the bag provided, you may use another bag or container available to store your used ring.
- Store used and unused rings in a private area out of reach of children.

TRANSPORT

Always bring all rings in your possession (used and unused) with you to the clinic. During transport, keep your rings with you at all times to avoid loss .

- Because this is an investigational study product, it is important to collect and properly dispose of all rings.

QUESTIONS OR CONCERNS

The study staff is here to help and support you. Please contact us between visits with any questions or concerns.

- If you have discomfort with the ring or any medical problems.
- If you need another ring, or have questions about any of the information provided to you.
- If the ring comes out or you take it out and have concerns about reinserting it or any difficulties putting it back in.
- If you have problems with your partner, relatives, or other people, that are related to your study participation or they have any questions.

Remember to use visual aids, such as a sample rings, pelvic models (if available), diagrammatic representations, bags for used ring collection, factsheets, and illustrations, as needed to help ensure participant understanding. Participants should be encouraged to ask questions and raise issues or problems at any time.