MTN-005 Eligibility Checklist

PTID: _____

Instructions: Use the table below to document a participant's eligibility for MTN-005 study participation. By writing your initials and date, you are documenting that the participant is eligible with regard to the inclusion/exclusion criterion listed on that row. Note that you may need to reference other source documents (i.e. Screening Behavioral Eligibility, Enrollment Behavioral Eligibility, Medical History, etc) in order to assess the item.

Inclusion and Exclusion Criteria	**Screening Visit Staff Init/Date**	**Enrollment Visit Staff Init/Date**
Age 18-45 years (inclusive) at Enrollment, verified per site standard operating procedures (SOP)		
Willing and able to provide written informed consent to be screened for and to take part in the study		
Willing and able to provide adequate locator information, as defined in site SOPs		
HIV-uninfected at Screening based on testing performed by study staff at Screening (per algorithm in Appendix II) and willing to receive HIV counseling and test results		
In general good health at Screening and Enrollment, as determined by the site Investigator of Record (IoR) or designee		
Per participant report at Screening and Enrollment, sexually active, defined as having had penile-vaginal intercourse at least once in the past 30 days prior to Screening and Enrollment		
Per participant report at Screening and Enrollment, expecting to continue penilevaginal intercourse at least monthly for the duration of study participation		
Per participant report, using an effective method of contraception at Enrollment, and intending to use an effective method for the duration of study participation. Effective methods include hormonal methods (except contraceptive vaginal rings), IUD inserted at least 7 days prior to enrollment, study provided male condoms, and/or sterilization (of participant or her sexual partner(s) as specified in site SOPs)		
Pap result in the 12 calendar months prior to Enrollment consistent with Grade 0 according to the Female Genital Grading Table for Use in Microbicide Studies, or satisfactory evaluation with no treatment required of non-Grade 0 Pap result per American Society for Colposcopy and Cervical Pathology (ASCCP) guidelines or per local standard of care, in the 12 calendar months prior to the Enrollment Visit		
At Screening and Enrollment, agrees not to participate in other drug or device research study for the duration of study participation		
Able and willing to abstain from the use of non-study vaginal products and/or practices (other than tampons) including but not limited to spermicides, diaphragms,contraceptive vaginal rings, vaginal antibiotic or antifungal medication, sex toys,lubricants or condoms that contain silicone, menstrual cup and douching, within the 14 days prior to Enrollment through study termination		
Participant reported history of: a. Adverse reaction to silicone (ever) b. Adverse reaction to latex (as defined per SSP) c. Adverse reaction to titanium dioxide d. Any current male sex partner with known history of adverse reaction to latex, silicone, titanium dioxide or any components of the study product (as defined per SSP) e. Last pregnancy outcome within 30 days or less prior to enrollment f. Hysterectomy		

Inclusion and Exclusion Criteria	Screening Visit Staff Init/Date	Enrollment Visit Staff Init/Date
At Screening or Enrollment, has a clinically apparent Grade 2 or higher pelvic exam finding (observed by study staff)[1]		
Pregnant at Screening or Enrollment, or per participant report intending to become pregnant during the period of study participation		
At Screening or Enrollment: a. Unwilling to comply with study participation requirements b. Has a clinically apparent deep disruption of vulvar, vaginal, or cervical epithelium (colposcopic findings not visible by naked eye are not exclusionary) c. Is diagnosed with a symptomatic urinary tract infection[2] d. Is diagnosed with a reproductive tract infection (RTI) or syndrome requiring treatment per current US Centers for Disease Control CDC) guidelines[2] e. Has any other abnormal physical or pelvic exam finding that, in the opinion of the investigator or designee, would contraindicate study participation		
At Screening or Enrollment, has condition that, in the investigator's opinion, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives		
Severe pelvic relaxation such that either the vaginal walls or the uterine cervix descend beyond the vaginal introitus with valsalva maneuver		
Participant report of 3 or more sexual partners in the month prior to Screening		

[1]Cervical bleeding associated with speculum insertion and/or specimen collection judged to be within the range of normal according to the clinical judgmentof the IoR/designee is considered expected non-menstrual bleeding and is notexclusionary.
Otherwise eligible participants with exclusionary pelvic examination findings may be enrolled/randomized after the findings have improved to a non-exclusionary severity grading or resolved. If improvement to a non-exclusionary grade or resolution is documented within 45 days of providing informed consent for Screening, the participant may be enrolled.

[2]RTIs requiring treatment, per site specific treatment guidelines, include BV, vaginal candidiasis, other vaginitis, trichomoniasis, chlamydia (CT), gonorrhea (GC), syphilis, active HSV lesions (HSV-2 seropositive women not excluded except with active lesions), chancroid, pelvic inflammatory disease, genital sores or ulcers, or cervicitis. Otherwise eligible participants diagnosed with RTI and/or UTI during Screening will be offered treatment or a prescription for treatment and may be enrolled after completing treatment and all symptoms have resolved. If treatment is completed and symptoms have resolved within 45 days of obtaining informed consent for Screening, the participant may be enrolled.