

Brief acceptability (FU2) CRF [Visit 3, 4, 5, 7, 8]

Note: Information in italics is for the interviewer and will not be read aloud to the participant.

To be used when contacting the participant via SMS or phone (or in-person, if preferred) between 24-72 hours after Visit 2 and Visit 6, as well as when contacting the participant via SMS or phone at 1 and 2 weeks after Visit 2, and 2 weeks after Visit 6.

These questions are intended to ask participants about their experience with the film after insertion and to offer support/guidance to address any challenges or concerns they have identified.

<p>1. Have you noticed the film in the last day/since you left the clinic? <i>Noticed can include if the participant felt, saw, or was aware of the film.</i></p>	<p><input type="checkbox"/> 1 Yes, describe: _____</p> <p><input type="checkbox"/> 2 No</p>
<p>2. Has the film bothered you or caused any discomfort? <i>If one is needed (such as significant discomfort), complete an AE form.</i></p>	<p><input type="checkbox"/> 1 Not at all → skip to Q4</p> <p><input type="checkbox"/> 2 Some</p> <p><input type="checkbox"/> 3 Quite a bit</p>
<p>3. In what ways has the film bothered you or caused discomfort?</p>	<p>Specify: _____</p>
<p>4. Have you noticed any changes to your vagina since using the film?</p>	<p><input type="checkbox"/> 1 Yes, describe: _____ _____</p> <p><input type="checkbox"/> 2 No</p>
<p>5. Do you have any concerns about using the film right now?</p>	<p><input type="checkbox"/> 1 Yes, <i>Specify</i>: _____</p> <p><input type="checkbox"/> 2 No</p>
<p><i>Asked only at Visits 4, 5, and 8 (one or two weeks after V2/V6)</i></p> <p>6. Have you inserted anything other than the film into your vagina since your last visit? <i>Read list and select each that apply</i></p>	<p><input type="checkbox"/> 1 Condom (male or female)</p> <p><input type="checkbox"/> 2 Tampons</p> <p><input type="checkbox"/> 3 Lubricants</p> <p><input type="checkbox"/> 4 Douches</p> <p><input type="checkbox"/> 5 Sex toys</p> <p><input type="checkbox"/> 6 Water (alone or with soap)</p> <p><input type="checkbox"/> 7 Vaginal medications</p> <p><input type="checkbox"/> 8 Vaginal moisturizers</p> <p><input type="checkbox"/> 9 Vaginal desiccants, to make the vagina dry or tight</p> <p><input type="checkbox"/> 10 Materials such as paper, cloth, or cotton wool</p> <p><input type="checkbox"/> 11 Other, specify: _____</p>
<p>7. <i>[At Visits 4 & 5 only: I know you were counseled to abstain from sex during the first month of film use, but I know sometimes sex doesn't only happen when we plan it].</i> <i>All visits: Have you had vaginal sex in the last week?</i></p>	<p><input type="checkbox"/> 1 Yes</p> <p><input type="checkbox"/> 2 No</p>
<p>8. Since you left the clinic, have you noticed the film coming out of your vagina, partially or fully?</p>	<p><input type="checkbox"/> 1 Yes, partially</p> <p><input type="checkbox"/> 2 Yes, fully</p> <p><input type="checkbox"/> 3 Not sure</p> <p><input type="checkbox"/> 4 No, not at all → skip to Q10</p>

<p>9. Please describe what you've noticed. <i>[Probes: when did this happen? What were you doing?]</i></p>	<p>Describe: _____</p>
<p>10. Is there anything you found positive or beneficial about the film so far?</p>	<p><input type="checkbox"/> ₁ Yes, describe: _____</p> <p><input type="checkbox"/> ₂ No</p>
<p>11. Do you have any questions for me?</p>	<p><input type="checkbox"/> ₁ Yes, describe the question the participant has, and any follow-up needed or counseling to be offered: _____ _____</p> <p><input type="checkbox"/> ₂ No</p>

END OF CRF

CRF Completed By: _____ (initials)

CRF Completion Date: ___ / ___ / _____ (dd/mm/yyyy)