





Follow-up behavioral and acceptability (FU3) CRF [Visit 6]

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

*The * next to some questions indicates a question (same or similar) also asked at baseline.*

<p>INTERVIEWER READS: The following questions ask you about your opinions and experiences with the vaginal film you used <u>over the past month</u>. Your honest opinions are very important in making sure we have the best information possible for developing HIV prevention products that will be liked and can be easily used by people like you.</p> <p>If the film came out after you inserted it, please do your best to respond with your opinions about the film while it was still in place in your vagina.</p>									
<p><i>Overall Product Acceptability</i></p>									
<p>1. *On a scale of 1 to 10, how much did you like or dislike using the vaginal film this past month, where 1 means extremely disliked and 10 means extremely well liked? <i>(Show Response Card 11)</i></p>									
									
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
¹ Extremely disliked ² Very disliked						⁹ Very well liked ¹⁰ Extremely well liked			
<p><i>Worries and excitement</i></p>									
<p>2. Please rate how easy or difficult it was for you to use the film (have it inserted in your vagina) in the last month, from 1-10, where 1 means extremely difficult and 10 means extremely easy. <i>(Show Response Card 12)</i></p>									
									
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
¹ Extremely difficult ² Very difficult						⁹ Very easy ¹⁰ Extremely easy			
<p>3. *On a scale of 1 to 10, how worried were you about the vaginal film in the last month, where 1 means extremely worried and 10 means not at all worried? <i>(Show Response Card 13)</i></p>									
									
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
¹ Extremely worried ² Very worried						⁹ Not worried ¹⁰ Not at all worried			
<p>4. *On a scale of 1 to 10, how excited were you when using the vaginal film in the last month, where 1 means not at all excited and 10 means extremely excited? <i>(Show Response Card 14)</i></p>									
									
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<p>¹Not at all excited ²Not excited</p>	<p>⁹Very excited ¹⁰Extremely excited</p>		
<p>5. How acceptable to you was the overall process of inserting the film? (<i>Show Response Card 15</i>)</p>	<p><input type="checkbox"/>₁ Not at all acceptable <input type="checkbox"/>₂ Not acceptable <input type="checkbox"/>₃ Somewhat acceptable <input type="checkbox"/>₄ Acceptable <input type="checkbox"/>₅ Highly acceptable</p>		
<p>6. How confident were you that the film was inserted correctly? (<i>Show Response Card 16</i>)</p>	<p><input type="checkbox"/>₁ Not at all confident <input type="checkbox"/>₂ Somewhat confident <input type="checkbox"/>₃ Fairly confident <input type="checkbox"/>₄ Very confident</p>		
<p>7. How confident were you that the film stayed in place over the past month? (<i>Show Response Card 16</i>)</p>	<p><input type="checkbox"/>₁ Not at all confident <input type="checkbox"/>₂ Somewhat confident <input type="checkbox"/>₃ Fairly confident <input type="checkbox"/>₄ Very confident <input type="checkbox"/>₅ N/A: <i>The film came out</i></p>		
<p>8. The next statements are about things that you may have experienced when you were using the vaginal film this month.</p>	<p>Yes (<i>Agree</i>)</p>	<p>No (<i>Disagree</i>)</p>	<p>N/A</p>
<p>a. *The vaginal film came out, or did not stay correctly in place 8.a.i. <i>If response=Yes, ask: What do you think caused that?</i> _____</p>	<p><input type="checkbox"/>₁</p>	<p><input type="checkbox"/>₂</p>	
<p>b. *The vaginal film felt uncomfortable during normal activities</p>	<p><input type="checkbox"/>₁</p>	<p><input type="checkbox"/>₂</p>	<p><input type="checkbox"/>₃</p>
<p>c. *The vaginal film felt painful during normal activities</p>	<p><input type="checkbox"/>₁</p>	<p><input type="checkbox"/>₂</p>	<p><input type="checkbox"/>₃</p>
<p>d. I thought a lot about the film over the last month</p>	<p><input type="checkbox"/>₁</p>	<p><input type="checkbox"/>₂</p>	
<p>e. *The vaginal film caused side effects</p>	<p><input type="checkbox"/>₁</p>	<p><input type="checkbox"/>₂</p>	
<p>f. *I felt like I could easily use the vaginal film as it was explained to me</p>	<p><input type="checkbox"/>₁</p>	<p><input type="checkbox"/>₂</p>	
<p>g. I did not notice the film during menses</p>	<p><input type="checkbox"/>₁</p>	<p><input type="checkbox"/>₂</p>	<p><input type="checkbox"/>₃</p>
<p>h. *The vaginal film made sex more enjoyable</p>	<p><input type="checkbox"/>₁</p>	<p><input type="checkbox"/>₂</p>	<p><input type="checkbox"/>₃</p>
<p>i. *The vaginal film caused pain during sex</p>	<p><input type="checkbox"/>₁</p>	<p><input type="checkbox"/>₂</p>	<p><input type="checkbox"/>₃</p>
<p>j. *It was exciting to use a new option that is being designed for HIV prevention</p>	<p><input type="checkbox"/>₁</p>	<p><input type="checkbox"/>₂</p>	
<p>k. *I felt like I had control over the vaginal film</p>	<p><input type="checkbox"/>₁</p>	<p><input type="checkbox"/>₂</p>	
<p>[<i>If 8e = Yes; skip otherwise</i>] 8e.i. Please describe the side effects you've experienced while using the vaginal film.</p>	<p><i>Specify:</i> _____</p>		
<p><i>Ease of use</i></p>			
<p>9. How long do you think it took for the film to dissolve in your vagina after insertion?</p>	<p>_____ days <input type="checkbox"/>₁ Do not think it dissolved fully</p>		




	<input type="checkbox"/> 2 Not sure																								
10. How often were you aware of the feeling of the vaginal film during your normal daily activities?	<input type="checkbox"/> 1 Most of the time <input type="checkbox"/> 2 Sometimes <input type="checkbox"/> 3 Never <input type="checkbox"/> 4 N/A																								
11. Over the last month, did you check to see if the vaginal film was still present in the vagina?	<input type="checkbox"/> 1 Yes <input type="checkbox"/> 2 No																								
12. Since the last visit, did you notice any of the following changes in your vagina? (Mark all that apply)	<input type="checkbox"/> 1 More wetness than normal <input type="checkbox"/> 2 More dryness than normal <input type="checkbox"/> 3 More itchiness than normal <input type="checkbox"/> 4 More soreness than normal <input type="checkbox"/> 5 Other: _____ <input type="checkbox"/> 6 No noticeable changes → skip to Q14																								
13. How, if at all, would the following changes in your vagina affect your use of vaginal films in the future? (Show Response Card 17) [Response option only included if selected in prior question]	<table border="1"> <thead> <tr> <th></th> <th>More likely to use</th> <th>No change in use</th> <th>Less likely to use</th> </tr> </thead> <tbody> <tr> <td>a. More wetness than normal</td> <td><input type="checkbox"/> 1</td> <td><input type="checkbox"/> 2</td> <td><input type="checkbox"/> 3</td> </tr> <tr> <td>b. More dryness than normal</td> <td><input type="checkbox"/> 1</td> <td><input type="checkbox"/> 2</td> <td><input type="checkbox"/> 3</td> </tr> <tr> <td>c. More itchiness than normal</td> <td><input type="checkbox"/> 1</td> <td><input type="checkbox"/> 2</td> <td><input type="checkbox"/> 3</td> </tr> <tr> <td>d. More soreness than normal</td> <td><input type="checkbox"/> 1</td> <td><input type="checkbox"/> 2</td> <td><input type="checkbox"/> 3</td> </tr> <tr> <td>e. Other: _____</td> <td><input type="checkbox"/> 1</td> <td><input type="checkbox"/> 2</td> <td><input type="checkbox"/> 3</td> </tr> </tbody> </table>		More likely to use	No change in use	Less likely to use	a. More wetness than normal	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	b. More dryness than normal	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	c. More itchiness than normal	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	d. More soreness than normal	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	e. Other: _____	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
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e. Other: _____	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3																						
Burden																									
14. *Since your last visit, how often did your use of the vaginal film interfere with any of your regular daily activities?	<input type="checkbox"/> 1 Most of the time <input type="checkbox"/> 2 Sometimes <input type="checkbox"/> 3 Never → skip to Q16 <input type="checkbox"/> 4 N/A → skip to Q16																								
15. Which daily activities were disrupted by film use?	_____																								
Adherence																									
<p>INTERVIEWER READS: I know you were counseled to abstain from sex during the first month of product use, and I know sometimes sex doesn't only happen when we plan it. I'm going to ask some questions about what you did in the past month, and it is important that we know what really happened – even if it is not what you were instructed to do. This will help us understand the results we get from this study. Your answers to these questions will not change your involvement in this study.</p>																									
16. Have you had any sex during the first month of film use, including oral, vaginal, or anal sex? Select all that apply	<input type="checkbox"/> 1 Oral <input type="checkbox"/> 2 Vaginal <input type="checkbox"/> 3 Anal <input type="checkbox"/> 4 None <input type="checkbox"/> 5 Other, specify: _____ <input type="checkbox"/> 6 Only non-receptive sex																								
Impact on Sex																									
<p>INTERVIEWER READS: I will now ask you some questions about sex, menstruation, and other vaginal practices in the last month. I know it can be awkward to talk about some of these things; I hope you feel comfortable to answer freely, and you can always skip questions if you would prefer.</p>																									

17. Did using the film affect...		Yes	No
a. How often you had any type of sex? <i>If yes: In what ways:</i> _____		<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
b. Your overall desire to have sex? <i>If yes: In what ways:</i> _____		<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
<i>If 16 = "4. None," or "6. Only non-receptive sex", skip to 27</i>			
c. Your feelings of intimacy or emotional closeness with your partner during sex? <i>If yes: In what ways:</i> _____		<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
d. The types of sex you had? <i>If yes: In what ways:</i> _____ _____		<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
18. How acceptable was the vaginal film's effect on: <i>(Show Response Card 18)</i> <i>Response options included only if selected "yes" in prior question</i>	Acceptable	Somewhat acceptable	Not acceptable
a. How often you had any type of sex	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
b. Your overall desire to have sex	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
c. Your feelings of intimacy or emotional closeness with your partner during sex	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
d. The types of sex you had	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
19. How did the film affect your sexual pleasure?	<input type="checkbox"/> ₁ It was not affected <input type="checkbox"/> ₂ I had less sexual pleasure than usual <input type="checkbox"/> ₃ I had more sexual pleasure than usual <input type="checkbox"/> ₄ N/A, film not present during sex → skip to Q23		
20. How did the film affect your partner(s)' sexual pleasure?	<input type="checkbox"/> ₁ It was not affected <input type="checkbox"/> ₂ They had less sexual pleasure than usual <input type="checkbox"/> ₃ They had more sexual pleasure than usual <input type="checkbox"/> ₄ I do not know <input type="checkbox"/> ₅ N/A, film not present during sex → skip to Q23		
21. Did your partner(s) notice the vaginal film at all?	<input type="checkbox"/> ₁ Yes, we talked about it <input type="checkbox"/> ₂ Yes, we did not talk about it, but I know they noticed it <input type="checkbox"/> ₃ No → skip to Q23 <input type="checkbox"/> ₄ N/A, film not present during sex → skip to Q23		

<p>22. Did your partner(s) notice any changes to your vagina related to you using the vaginal film? <i>Mark all that apply</i></p>	<p><input type="checkbox"/> 1 Change in taste <input type="checkbox"/> 2 Change in scent or smell <input type="checkbox"/> 3 Change in lubrication <input type="checkbox"/> 4 Other, <i>specify:</i> _____ <input type="checkbox"/> 5 No changes <input type="checkbox"/> 6 I don't know</p>
<p>23. <i>(Skip unless 16=2 (had vaginal sex))</i> How often did you use condoms when having vaginal sex, since inserting the-vaginal film?</p>	<p><input type="checkbox"/> 1 Always <input type="checkbox"/> 2 Sometimes <input type="checkbox"/> 3 Rarely <input type="checkbox"/> 4 Never</p>
<p>24. Did any film come out when you had sex?</p>	<p><input type="checkbox"/> 1 Yes <input type="checkbox"/> 2 No <input type="checkbox"/> 3 Not sure <input type="checkbox"/> 4 <i>N/A, film not present during sex</i></p>
<p>25. Did you use a condom the last time you had vaginal sex?</p>	<p><input type="checkbox"/> 1 Yes <input type="checkbox"/> 2 No</p>
<p>26. Overall, how did you feel about the film being present during sex?</p>	<p><input type="checkbox"/> 1 Liked it <input type="checkbox"/> 2 Did not like it <input type="checkbox"/> 3 No opinion <input type="checkbox"/> 4 <i>N/A, film not present during sex</i></p>
<p>27. Have you inserted anything 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) <input type="checkbox"/> 2 Tampons <input type="checkbox"/> 3 Lubricants <input type="checkbox"/> 4 Douches <input type="checkbox"/> 5 Sex toys <input type="checkbox"/> 6 Water (alone or with soap) <input type="checkbox"/> 7 Vaginal medications <input type="checkbox"/> 8 Vaginal moisturizers <input type="checkbox"/> 9 Vaginal desiccants, to make the vagina dry or tight <input type="checkbox"/> 10 Materials such as paper, cloth, or cotton wool <input type="checkbox"/> 11 Other, <i>specify:</i> _____</p>
<p><i>Use during menses</i></p>	
<p>28. In the past month, have you had any vaginal bleeding or spotting?</p>	<p><input type="checkbox"/> 1 Yes <input type="checkbox"/> 2 No → skip to Q32</p>
<p>29. Was the vaginal bleeding expected (usual menses) or unexpected?</p>	<p><input type="checkbox"/> 1 Expected <input type="checkbox"/> 2 Unexpected</p>
<p>30. How did you feel about the film being present during bleeding?</p>	<p><input type="checkbox"/> 1 I liked using it during bleeding <input type="checkbox"/> 2 I did not like using it during bleeding <input type="checkbox"/> 3 No opinion <input type="checkbox"/> 4 <i>N/A, film not present during bleeding → skip to Q32</i></p>

<p>31. Was the film disrupted during bleeding? Disrupted could mean displaced/moved/shifted a little in the vagina or completely came out.</p>	<input type="checkbox"/> ₁ Yes, <i>specify:</i> _____ <input type="checkbox"/> ₂ No <input type="checkbox"/> ₃ Not sure
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Product attributes

32. For each of the following, what is your opinion of... (<i>show Response Card 19</i>)	 I liked it/ No problem	 Neutral/ No opinion	 I did not like it/ It was a problem
a. How the vaginal film is inserted	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
b. How the vaginal film felt during insertion	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
c. How the vaginal film felt after it was inserted	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
d. The size of the vaginal film	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
e. How long the protection would last (i.e. one month of protection)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
f. How the vaginal film looks	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
g. How using the vaginal film affected your body	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
h. Vaginal film side effects	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
i. How quickly the vaginal film dissolved	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
j. Any remaining film (<i>This could mean amount, color, or texture</i>)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
k. Any increases to vaginal wetness caused by the film	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
l. The color of the film	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
m. The smell of the film	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
n. The shape of the film	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
o. The vaginal film's ability to be kept discreet from others?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃

Satisfaction

33. Please rate on a scale of 1-10 how satisfied you are, overall, with using the vaginal film, where 1 means extremely dissatisfied and 10 means extremely satisfied. (*Show Response Card 20*)

									
<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆	<input type="checkbox"/> ₇	<input type="checkbox"/> ₈	<input type="checkbox"/> ₉	<input type="checkbox"/> ₁₀

¹ Extremely dissatisfied ² Very dissatisfied	⁹ Very satisfied ¹⁰ Extremely satisfied
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END OF CRF

CRF Completed By: _____ (initials)

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