

[Introductory Statement]: Hello, my name is *[Interviewer's name]* and I'll be your interviewer today. I want to begin by thanking you for taking the time to talk with me. Your experience and thoughts about the study are very valuable to future research so we really appreciate you taking the time to complete this interview today.

Some of the questions are sensitive but everything we discuss will be kept confidential. Audio from our session will be recorded and transcribed, but key identifiable information—such as names or places—will be made anonymous to protect your privacy. Any question you would rather not answer let me know and we can skip it. You have the right to withdraw at any point in the study. In total the interview should last about an hour.

In case of an adverse event or social harm that is reported during the interview, I will encourage you to report that information to clinical staff if you haven't already done so. I will also report an adverse event or social harm to study staff. An example of an adverse event is an undesirable experience associated with the insert such as an allergic reaction. An example of a social harm is experiencing difficulties in personal relationships as a consequence of study participation.

Do you have any questions before we get started?

My first few questions ask how you feel about the study broadly, but before we get into that I just want to stress that we're looking for feedback, whether it be good or bad. We really want to know what you think, so please don't hold back with your responses and answer as honestly as possible.

<u>Section</u>	<u>Topic</u>	<u>Prompt</u>	<u>Probe</u>	<u>Notes</u>
1. General Study Experiences	1.1 General experience and motivation for participating in the study.	Overall, how would you describe your experience participating in the study?	a) How was your experience with the clinic staff? b) How was your experience with the study procedures? c) How did you feel about the different medical and laboratory procedures? d) You were asked to use an enema prior to your study visits, how was your experience using the enema? e) Did you have any difficulties during the study? a. Tell me more about that.	<i>Interviewer:</i>

[Transition]: Now I want to switch gears and talk about your experiences using the insert and any problems you may have experienced.

<p>2. Study Insert Experiences.</p>	<p>2.1 General experiences with the insert.</p>	<p>Please share in detail your experiences with the rectal insert used in this study.</p>	<ol style="list-style-type: none"> 1. How did the insertion of the product go the first time? <ol style="list-style-type: none"> a. How did you feel during the insertion process? b. How do you feel while you waiting for the insert(s) to dissolve? c. What, if anything, did you feel after the product dissolved? 2. How, if at all, did things change when you had to use two inserts? 3. Let's talk about your experience using the two doses of the insert. <ol style="list-style-type: none"> a. How did you feel during the insertion process? b. How do you feel while you waiting for the insert(s) to dissolve? c. What, if anything, did you feel after the product dissolved? 	
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	2.2 General issues with insert.	Did you have any problems with the insert during the study?	<p>If YES:</p> <ul style="list-style-type: none"> • What happened? • How, if at all, did you resolve the problem? <p>If NO:</p> <ul style="list-style-type: none"> • Do you feel like you did anything specific that may have helped to prevent having any problems? 	Interviewer:
	2.3 Perceptions regarding the study insert.	How do you feel about the insert overall?	<ol style="list-style-type: none"> 1. What, if anything, did you like about the insert? 2. What, if anything, did you dislike about the insert? 3. Did you experience any leakage after using the insert? <ul style="list-style-type: none"> a. (If yes...) Can you tell me about the leakage that occurred? 4. Did you experience a bowel movement or urge to have a bowel movement immediately after using the insert? 5. Were there any unexpected benefits with using this insert? 	
<p>[Transition]: Next we will talk about how well you liked the insert.</p>				

4. Social Influence	4.1 Insert discussions and social influence.	Outside of the clinic staff, did you talk to anyone about the insert?	<p>NO:</p> <ul style="list-style-type: none"> • Were there any reasons in particular that led you not to talk to anyone about the insert? • If you had talked to someone, what would you have told them about the insert? <p>YES:</p> <ul style="list-style-type: none"> • What did you talk about? • Who did you talk to? • What did they ask about the insert? • How did they feel about your participation in the study? • What would you tell other men or women about the insert? 	
	4.3 Perceived ability to talk about the insert with a sex partner.	How comfortable did you feel discussing using the study insert with your sex partner(s)?	<p><i>[If participant says he/she DID NOT discuss with partner]</i></p> <ul style="list-style-type: none"> • How would you describe the product? <ul style="list-style-type: none"> ○ How would you bring it up? ○ What would you say? ○ When would you bring it up? • What would make talking about the insert easier? <p><i>[If participant says he/she DID discuss with partner]</i></p> <ul style="list-style-type: none"> • Tell me about that conversation. • What did you talk about? • How did your partner respond? 	

	4.5 Perceived factors of insert adherence for anal sex.	Thinking about your own life experiences, what issues would prevent you from using the insert for anal sex?	<ul style="list-style-type: none"> Types of partner? (casual partner, committed relationship, one-time partner, etc). Receptive vs insertive sex role? 	Interviewer:
	4.6 Insert recommendations	Would you recommend the insert to others?	Why?	
[Transition]: Moving on to our final section, we're going to talk about insert design.				
5. Insert Product Marketing.	5.1 Insert design by participant.	We'd like to ask you to imagine that you are the marketing director for the study insert. Having used the product, how would you present this product to the public?	<ul style="list-style-type: none"> What would you call this product? Who would be your key audience? How you would describe the product to your peers in order to convince them to try it out. What negative qualities of the insert could be improved? 	
[Transition]: So that's everything we have for you today, but before we part ways, I wanted to ask...				
6. Conclusion	6.1 Is there any part of your experience with the insert that we didn't have a chance to talk about?			
	6.2 Is there anything we did ask about that we should have asked differently?			
	6.3 Do you have any further questions or comments?			
[Concluding Statement]: That's all the questions I have. Thank you so much for taking the time to talk with me today.				