6. **Please check all the activities during the patient felt pain:** ***Check ALL that apply***

- ☒ Menstruation
- ☐ Urination
- ☒ Intercourse
- ☐ Bowel Movement
- ☐ Usual recreation activities
- ☐ Usual child care activities
- ☐ Other: ______________________

7. **Has the patient had any unusual health related events ~~occur~~ since the last contact ?**

☒ Yes ☒ No → ***If no, skip to Question 8***

LR 2/13/02

Please summarize the events briefly below, and enter the specifics of the event on the AE Form.

~~See about 9-01 LR 1/29/02~~
~~Tightness in (R) lower back x 2-3 mos. Lifts weights~~
~~in Nov 01 during preg. test, Bradley ordered~~
~~transv. US.~~ LR 2/13/02

Is Question 18 on Part 1 of this form also marked 'Yes'? If not, please do so, as this information must be consistent.

Have the AE's listed above been entered on the AE form? ☐ Yes

8. **How does the patient rate the comfort of wearing the device:**

☒ Excellent ☐ Good ☐ Fair ☐ Very Good ☐ Poor

9. **How satisfied is the patient with the device overall ?**

- ☒ Very satisfied
- ☐ Somewhat satisfied
- ☐ Neither satisfied or dissatisfied
- ☐ Somewhat dissatisfied
- ☐ Very dissatisfied

10. **Has the patient had at least 4 coital acts each month since the last contact ?**

If Yes, Skip to Question 11 ← ☒ Yes ☐ No ↓ ***Complete the information below***

If no, please enter the total number of months since the last contact (usually 6) : ________

Enter the number of the above months that the patient DID NOT have at least 4 coital acts: ______

If Unknown, enter the average number of coital acts that the patient has per month: ______

Provide any information on extenuating circumstances below (i.e. separation, partner out of town, etc.)

____

____

CRA:	Date:	CRA:	Date:	CRA:	Date:
[illegible]	3/13/02				

		☐ Other, please describe:
11	Did the participant experience any other changes in her usual state of health since the last scheduled contact? **If Yes, please complete the "Adverse Events" form (AE).**	☒ No (Yeast 11/14/00) ☒ Yes. Please describe: Pelvic cramping & pain, yeast infection (2) low back pain, sinus
12	How does the participant rate the comfort of wearing the device?	list 2 5
13	How does the participant rate her overall satisfaction with the device?	list 3 5
14	Did the participant complete her diary for the past 3 months? **If No, please instruct the participant to complete the diary immediately.**	☒ Yes ☐ No
15	Has the participant been instructed to discontinue use of temporary contraception?	☒ Yes. Date instruction given: 2 / 28 / 01 (2000-2002) ☐ No. Please comment:

16	Has the participant had at least four coital acts per month for the past 3 months?	☐ No ☒ Yes
17	Was contraception used during each coital act?	☐ No ☒ Yes
18	Has the participant changed sexual partners?	☒ No ☐ Yes
19	Has the participant's partner had any procedure that may impact his fertility, such as orchiectomy, prostatectomy, or vasectomy?	☒ No ☐ Yes
20	Has the participant had an intrauterine procedure, such as endometrial biopsy, D&C, or hysteroscopy (diagnostic or operative) including endometrial ablation or resection?	☒ No ☐ Yes

12	Has the participant bled between menses since the last contact? If Yes, indicate duration and severity of most significant episode.	X No C Yes. Specify number of times occurred since last contact: ___ Specify duration: list 1 Specify severity: list 2
13	How does the participant describe her menstrual flow as compared to her normal menses?	list 3 2
14	Type of Pregnancy Test Administered	X Urine C Serum
15	Pregnancy Test Results. **If Positive, contact Conceptus within 24 hours.**	Date performed: 2 / 12 / 01 (2000-2002) Result: C Positive X Negative
16	Has either STOP device come out of the participant's body? **If Yes, please call Conceptus within 24 hours and complete "Expulsion or Migration" form (ExpMig) and "Adverse Events" form (AE).**	X No C Yes
17	Did the participant experience any adverse events. **If Yes, please complete the "Adverse Events" form (AE).**	C No X Yes 11/14/01
	Instruction: Please continue data entry for this visit on the VstPDP2 page.	

Pulldown-List 1	Pulldown-List 2	Pulldown-List 3
1= Less than 1 day 2= 1 - 2 days 3= 3 - 4 days 4= 5 - 7 days	1= Spotting 2= Light bleeding 3= Moderate bleeding 4= Heavy bleeding	1=Less than normal 2=Same as normal 3=More than normal