

1. PARENT INFORMATION

MOTHER FATHER

Country: **UNITED STATES** Patient's Initials: Date of Birth: Age: **30 Year[s]** Race: **Not Available**

2. PREGNANCY HISTORY (For previous pregnancies only)

Pregnancy Number	Year	Outcome:

Relevant medical history (including family history)

3. SUSPECT DRUG(S)

Generic Name	Brand Name	Admin. Route	Unit Dose	Frequency	Daily Dose	Start Date	Stop Date	Batch No.	Indication	Trimester Exposed	Action Taken
	MIRENA	Intra-uterine					Unknown	535960	Contraception		

4. CONCOMITANT MEDICATIONS

Generic Name	Brand Name	Admin. Route	Unit Dose	Frequency	Daily Dose	Start Date	Stop Date	Indication	Via	Action Taken

5.1 ADVERSE EVENTS AND CASE NARRATIVE

Adverse Event (s)	Gestation time at onset date (Weeks)	Start Date	Stop Date	Ongoing
1. 10061178 - Genital haemorrhage			Unknown	Unknown
2. 10000081 - Abdominal pain			Unknown	Unknown
3. 10063130 - Pregnancy with contraceptive device			Unknown	Unknown

5.2 CASE NARRATIVE (Please provide full details of the pregnancy and/or event)

6. SERIOUSNESS AND OUTCOME

<input checked="" type="checkbox"/> Not Serious Seriousness <input type="checkbox"/> Did the patient die? Death Date: <input type="checkbox"/> Autopsy <input type="checkbox"/> Was hospitalization required or prolonged? Date: <input type="checkbox"/> Did the AE cause a disability? <input type="checkbox"/> Did the AE cause a congenital anomaly? <input type="checkbox"/> Was the AE life threatening? <input type="checkbox"/> Medically serious	Reporter's Causality (if Health Care Professional) YES Outcome
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7. Pregnancy Information

Contraceptive Use:	Please specify:
Last Menstrual Period (Date):	Estimated Due Date:
Outcome Elective Abortion	Date
Remarks (indication, lab result, etc.)	
Type of pregnancy Type: If Other:	
Prenatal radiation dose limit for full duration of pregnancy Dose Limit: Unit:	
Dosage 1 Start: End: Taken: Dosimeter: Comment:	
Dosage 2 Start: End: Taken: Dosimeter: Comment:	

