

5.2A ADVERSE EVENT FORM

Date of Visit: (MM/DD/YEAR) ___/___/____ Clinic ID #: _____ Provider ID #: _____

Contraceptive Method _____ (if IUD, specify type _____)

Reason for visit: Routine visit Charge follow-up High-volume site Low-volume site Clinic request
 Adverse event follow-up Inventory/reordering concern Other _____

Severe Adverse Event (select all that apply):

IUD perforation

How was the perforated IUD removed? (select all that apply) Removed through the vagina Laparoscopy
 Hysteroscopy Laparotomy Other (describe below)

Were there other complications from the perforated IUD? (select all that apply)

None Perforated bowel Perforated bladder Hemorrhage Hysterectomy Other (describe below)

Hospitalization related to Z-CAN provided contraception

Diagnosis of Pelvic Inflammatory Disease (PID) in an IUD user ▶ IUD NOT removed IUD removed

Venous thromboembolism (deep vein thrombosis, pulmonary embolism)

Ectopic pregnancy (at Return Visit) ▶ Had patient stopped contraception to achieve pregnancy? Yes No

Please provide a brief description of the Severe Adverse Event with additional details not captured above:

Adverse Event, including device event (select all that apply):

IUD expulsion ▶ Partial (within cervical canal) Complete (IUD out of uterus and cervix)

Failed IUD insertion ▶ device NOT contaminated device contaminated (▶ go to Product Documentation)

Skin infection around implant insertion site ▶ Implant NOT removed Implant removed

Deep implant/Need for alternative measures for implant removal

Pregnancy (at Return Visit) ▶ Had patient stopped contraception to achieve pregnancy? Yes No

Broken implant

Product Documentation (Record product contaminated or product used that patient never left clinic with)

Type _____ Lot # _____ Exp. Date _____

Other (describe below)

Please provide a brief description of the Adverse Event (or device event) with additional details not captured above:

Was the patient seen at an outside location for management of this adverse event? Yes No

If Yes ▶ Where? ER Hospital Another Z-CAN Provider (please specify below) Other (please specify below)

Was the patient referred to another physician for this adverse event? Yes No

If Yes ▶ Who? Assigned Consultant* Another Z-CAN Provider (please specify below)

* Reminder: Obtain authorization from the assigned consultant prior to referring patient.

Did the patient leave clinic today with a contraceptive method? (remember to fill out Initial or Return Visit Form)

Yes ▶ please indicate method _____

No ▶ please indicate method _____

Do not include any personally identifiable patient information on this form (e.g. patient name, medical record number, phone number, e-mail address, mailing address, or date of birth)

Physician Initials: _____ and License #: _____

Please submit to the Z-CAN Program within 24 hours • For Severe Adverse Events, call the administrative doctor within 24 hours