Appendix 1. Sterilization/Long-Acting Reversible Contraceptives (LARC) Core Minimum Dataset

MEDICAL HISTORY		
Reproductive/ Gynecological History (5)	Pregnancy History - Number of Previous Pregnancies Pregnancy History - Outcome of Previous Pregnancies (e.g., miscarriage, ectopic, etc.) Currently Breastfeeding? (Y/N) Menstruation History - Regular Cycles? (Y/N) Prior Conditions or Symptoms (specific conditions below) (Y/N) Intracyclic bleeding (Y/N) Dysmenorrhea (Y/N) Pelvic Pain (Y/N) Endometriosis (Y/N) Dyspareunia (Y/N) Adenomyosis (Y/N) Fibroids (Y/N)	Pelvic inflammatory disease (PID) (Y/N) Breast Cancer (Y/N) Anovulatory Condition (Y/N) Cervical Conization (e.g., cone biopsy, LEEP procedure) (Y/N) Prior Sexually Transmitted Disease (STD - e.g., Gonorrhea, Syphilis, Chlamydia, Other prior STD) (Y/N) Gynecological Cancer (e.g., uterine cancer, ovarian cancer, cervical cancer) (Y/N) Acute cervicitis, vaginitis, or other lower genital tract infection (Y/N) Uterine abnormality that distorts cavity (Y/N) Absence of menstrual bleeding (Y/N)
Surgical History (4)	Any prior intra-abdominal surgery? (Y/N) If yes, laparoscopic or open?	Any prior vaginal/hysteroscopic/cervical surgery? (Y/N) If yes, which type of vaginal/ hysteroscopic/cervical surgery? (e.g., endometrial ablation, etc.)
General Medical History (7)	History of chronic pain (e.g., fibromyalgia) (Y/N) Prior Psychiatric Disorders (e.g., Depression, Anxiety, etc.) (Y/N) Autoimmune disease (Y/N) Bleeding disorder (Y/N)	Prior allergic or hypersensitivity reaction possibly or definitely related to materials/ substances used in the index procedure (Y/N) If yes, what was the reaction to? (e.g., metal, latex, etc.) (open-ended response) If yes, what was the reaction? (e.g., rash, hives, etc.) (open-ended response)
PROCEDURE DATA: **Index Procedure, Post-procedure Follow-up**		
General Encounter Information (16)	On what date was the index procedure performed? During which time period was this performed? (select one of the options indented below) Interval (more than 6 weeks from delivery/abortion or unrelated to delivery) Post-abortal (same day as abortion / confirmation of abortion) Post-partum (if yes, select one of the options indented below) Post-placental (within 30 minutes of delivery) Prior to hospital discharge and more than 30 minutes after delivery After hospital discharge AND within 6 weeks of delivery Encounter Reason (e.g., New Sterilization/LARC Procedure, Post-Procedure Follow-up, etc.) Procedure Performed (e.g., Total	Facility where procedure was performed Provider ID Number of Procedures Performed by the Provider in Last Six Months (same procedure performed that was listed above) Pre-procedure imaging? (Y/N) If yes, type of procedure? (e.g., Transvaginal Ultrasound, Hysterosalpingogram, etc.) Inter-procedure imaging? (Y/N) If yes, type of procedure? (e.g., Transvaginal Ultrasound, Hysterosalpingogram, etc.) Post-procedure imaging? (Y/N) If yes, type of procedure? (e.g., Transvaginal Ultrasound, Hysterosalpingogram, etc.) If yes, Post-Procedure Indication for Diagnostic Imaging (for all sterilization/ LARC procedures) If yes, were post-sterilization imaging results satisfactory for reliance on device for sterilization? (Y/N)

	Salpingectomy, Partial Salpingectomy, etc.)	
Other Procedures Performed in Conjunction with Sterilization Procedure (1)	Concomitant Procedures (e.g., c-section, hysteroscopic myomectomy, hysteroscopic polypectomy, hysteroscopic ablation, D&C, laparoscopic adnexal surgery, other)	
Procedure Elements (Index Procedure or Follow-up) (7)	Product ID (e.g., Unique Device Identifier (UDI), National Drug Code (NDC)) Placement Success Achieved (Y/N) Fallopian Tube Treated - for hysteroscopic & surgical sterilizations only (e.g., Left, Right, Bilateral) Successful Visualization of Right/Left Tubal Ostia - for hysteroscopic sterilizations only (Y/N)	Primary Reason for Unsuccessful Placement (e.g., Procedure-related adverse event, poor distension, poor visualization, etc.) Intraoperative Findings - for hysteroscopic and surgical sterilizations only (e.g., Adhesions, Adnexal Mass, Fibroids, Endometriosis, etc.) Number of unsuccessful procedure attempts (for each unsuccessful attempt, specify reason)
Product Removal Procedure-Specific Elements (7)	Unintended Removal by health care provider (e.g., During Dilation and Curettage, etc.) Planned Removal (Y/N) Reason for planned removal (e.g., Unable to rely on device, Pain, Bleeding, etc.) Other procedures performed with removal (e.g., Incisional Sterilization, Hysteroscopy, etc.)	Complete Device Removal (e.g., Intact Device, All Fragments Removed, N/A) Partial Removal (e.g., Device Breakage Prior to Removal, etc.) Any device or implant abnormalities (Y/N)
MEDICATIONS		
Medications (20)	Pre-procedural Medication (Y/N) If yes, enter Medication Name (pain medication, anesthesia, etc.) If yes, enter Indication If yes, enter Start Date If yes, enter End Date Procedural Medication (Y/N) If yes, enter Medication Name (pain medication, anesthesia, etc.) If yes, enter Indication If yes, enter Start Date If yes, enter End Date	Discharge Medication (Y/N) If yes, enter Medication Name (pain medication, anesthesia, etc.) If yes, enter Indication If yes, enter Start Date If yes, enter End Date Follow-up Medication (Y/N) If yes, enter Medication Name (pain medication, anesthesia, etc.) If yes, enter Indication If yes, enter Start Date If yes, enter End Date
ENDPOINTS DURING AND AFTER TREATMENT		

Events or Complications - Permanent Hysteroscopic Sterilization (23)	Hematoma formation (Yes/No | Procedure/Post-procedure | Date) Device expulsion (Yes/No | Procedure/Post-procedure | Date) Device malposition/migration/dislocation (Yes/No | Procedure/Post-procedure | Date) Nerve injury (Yes/No | Procedure/Post-procedure | Date) Thermal injury (Yes/No | Procedure/Post-procedure | Date) Visceral organ injury (Yes/No | Procedure/Post-procedure | Date) Perforation (Yes/No | Procedure/Post-procedure | Date | Specify Organ perforated) Vascular injury (Yes/No | Procedure/Post-procedure | Date) Venous thrombosis within 30 days of procedure (Yes/No | Procedure/Post-procedure | Date) Pulmonary Embolism within 30 days of procedure (Yes/No | Procedure/Post-procedure | Date) Pain requiring prescriptive medication (Yes/No | Procedure/Post-procedure | Date)	Vasovagal syncope or seizure on day of placement (Yes/No | Procedure/Post-procedure | Date) Pelvic inflammatory disease (PID) (Yes/No | Procedure/Post-procedure | Date) Other Infection (Yes/No | Procedure/Post-procedure | Date) Anesthesia-related event (Yes/No | Procedure/Post-procedure | Date) Inability to access fallopian tubes during procedure (Yes/No) Nausea or vomiting (Yes/No | Procedure/Post-procedure | Date) Fainting or dizziness (Yes/No | Procedure/Post-procedure | Date) Surgical hemorrhage (Yes/No) Other medical product related adverse event (AE) (Yes/No | Procedure/Post-procedure | Date) If yes, specify Other procedure related AE (Yes/No | Procedure/Post-procedure | Date) If yes, specify
Events or Complications - All Other Permanent Surgical Sterilization (24)	Hematoma formation (Yes/No | Procedure/Post-procedure | Date) Device expulsion (Yes/No | Procedure/Post-procedure | Date) Device malposition/migration/dislocation (Yes/No | Procedure/Post-procedure | Date) Nerve injury (Yes/No | Procedure/Post-procedure | Date) Thermal injury (Yes/No | Procedure/Post-procedure | Date) Visceral organ injury (Yes/No | Procedure/Post-procedure | Date) Perforation (Yes/No | Procedure/Post-procedure | Date | Specify Organ perforated) Vascular injury (Yes/No | Procedure/Post-procedure | Date) Venous thrombosis within 30 days of procedure (Yes/No | Procedure/Post-procedure | Date) Pulmonary Embolism within 30 days of procedure (Yes/No | Procedure/Post-procedure | Date) Pain requiring prescriptive medication (Yes/No | Procedure/Post-procedure | Date)	Vasovagal syncope or seizure on day of placement (Yes/No | Procedure/Post-procedure | Date) Subcutaneous emphysema (Yes/No | Procedure/Post-procedure | Date) Pelvic inflammatory disease (PID) (Yes/No | Procedure/Post-procedure | Date) Other Infection (Yes/No | Procedure/Post-procedure | Date) Anesthesia-related event (Yes/No | Procedure/Post-procedure | Date) Inability to access fallopian tubes during procedure (Yes/No) Nausea or vomiting (Yes/No | Procedure/Post-procedure | Date) Fainting or dizziness (Yes/No | Procedure/Post-procedure | Date) Surgical hemorrhage (Yes/No) Other medical product related AE (Yes/No | Procedure/Post-procedure | Date) If yes, specify Other procedure related AE (Yes/No | Procedure/Post-procedure | Date) If yes, specify

Events or Complications - LARC – Contraceptive Implants (15)	Hematoma formation (Yes/No | Procedure/Post-procedure | Date) Device expulsion (Yes/No | Procedure/Post-procedure | Date) Device malposition/migration/dislocation (Yes/No | Procedure/Post-procedure | Date) Nerve injury (Yes/No | Procedure/Post-procedure | Date) Vascular injury (Yes/No | Procedure/Post-procedure | Date) Venous thrombosis within 30 days of procedure (Yes/No | Procedure/Post-procedure | Date) Pain requiring prescription medication (Yes/No | Procedure/Post-procedure | Date)	Deep placement of implant (Yes/No | Procedure/Post-procedure | Date) Other Infection (Yes/No | Procedure/Post-procedure | Date) Fainting or dizziness (Yes/No | Procedure/Post-procedure | Date) Surgical hemorrhage (Yes/No) Other medical product related AE (Yes/No | Procedure/Post-procedure | Date) If yes, specify Other procedure related AE (Yes/No | Procedure/Post-procedure | Date) If yes, specify
Events or Complications - LARC – Intrauterine Devices (18)	Hematoma formation (Yes/No | Procedure/Post-procedure | Date) Device expulsion (Yes/No | Procedure/Post-procedure | Date) Device malposition/migration/dislocation (Yes/No | Procedure/Post-procedure | Date) Nerve injury (Yes/No | Procedure/Post-procedure | Date) Visceral organ injury (Yes/No | Procedure/Post-procedure | Date) Perforation (Yes/No | Procedure/Post-procedure | Date | Specify Organ perforated) Vascular injury (Yes/No | Procedure/Post-procedure | Date) Venous thrombosis within 30 days of procedure (Yes/No | Procedure/Post-procedure | Date) Pain requiring prescription medication (Yes/No | Procedure/Post-procedure | Date)	Vasovagal syncope or seizure on day of placement (Yes/No | Procedure/Post-procedure | Date) Pelvic inflammatory disease (PID) (Yes/No | Procedure/Post-procedure | Date) Other Infection (Yes/No | Procedure/Post-procedure | Date) Nausea or vomiting (Yes/No | Procedure/Post-procedure | Date) Fainting or dizziness (Yes/No | Procedure/Post-procedure | Date) Other medical product related AE (Yes/No | Procedure/Post-procedure | Date) If yes, specify Other procedure related AE (Yes/No | Procedure/Post-procedure | Date) If yes, specify
Pregnancy (20)	Date of confirmation of pregnancy Gestational age at presentation (in weeks) Estimated due date (relatively easy to calculate and can be done at the time of presentation) Pregnancy outcome: Ectopic (Y/N) If yes, date of diagnosis If yes, treatment Intrauterine (Y/N) (if yes, provide date) If yes, date of presentation If yes, gestational age at presentation If yes, type (select from following options)	Termination of pregnancy If yes, trimester (first, second, third) Miscarriage/fetal demise (e.g. Intra Uterine Fetal Death (IUFD) If yes, trimester (first, second, third) Other abnormal pregnancy (e.g. molar) If yes, trimester (first, second, third) Delivery If yes, choose preterm or term If yes, choose vaginal delivery, cesarean section, or operative delivery
Methods for Evaluations of Endpoints (2)	Did event meet criteria for a serious adverse event? (Y/N - Criteria: Death; Life-Threatening; Hospitalization Required; Prolonged hospitalization; Congenital Anomaly or birth defect; Persistent Disability or Incapacity)	Outcome of Treatment of AE (e.g., Recovered, Recovered with Unresolved Sequelae, etc.)

Note: This table originally appeared in The Women's Health Technologies Coordinated Registry Network (WHT-CRN) report.[14]