

Supplemental File 2. Sterilization/ LARC Core Minimum Dataset – Consensus Level for Each Delphi Round*

*If Round 1 consensus is not reported, this is because the variable was introduced in Round 2

*If Round 2 consensus is not reported, this is because the variable was introduced in discussions following the Round 2 survey

MEDICAL HISTORY		ROUND 1 RESULTS	ROUND 2 RESULTS
Reproductive/ Gynecological History (5)	Pregnancy History - Number of Previous Pregnancies	100%	92%
	Pregnancy History - Outcome of Previous Pregnancies (e.g., miscarriage, ectopic, etc.)	100%	100%
	Currently Breastfeeding? (Y/N)	50%	85%
	Menstruation History - Regular Cycles? (Y/N)	80%	54%
	Prior Conditions or Symptoms (specific conditions below) (Y/N)	100%	77%
	Intracyclic bleeding (Y/N)	70%	67%
	Dysmenorrhea (Y/N)	80%	92%
	Pelvic Pain (Y/N)	100%	100%
	Endometriosis (Y/N)	70%	92%
	Dyspareunia (Y/N)	70%	75%
	Adenomyosis (Y/N)	50%	75%
	Fibroids (Y/N)	80%	92%
	Pelvic inflammatory disease (PID) (Y/N)	60%	92%
	Cervical Conization (e.g., cone biopsy, LEEP procedure) (Y/N)	70%	58%
	Prior Sexually Transmitted Disease (STD -e.g., Gonorrhea, Syphilis, Chlamydia, Other prior STD) (Y/N)	60%	58%
	Breast Cancer (Y/N)	70%	58%
	Gynecological Cancer (e.g., uterine cancer, ovarian cancer, cervical cancer) (Y/N)	80%	75%
Acute cervicitis, vaginitis, or other lower genital tract infection (Y/N)	50%	58%	
Uterine abnormality that distorts cavity (Y/N)	80%	67%	
Absence of menstrual bleeding (Y/N)	50%	50%	
Anovulatory Condition (Y/N)		67%	
Surgical History (4)	Any prior intra-abdominal surgery? (Y/N)		100%
	If yes, laparoscopic or open?		69%
	Any prior vaginal/hysteroscopic/cervical surgery? (Y/N)		100%
If yes, which type of vaginal/hysteroscopic/cervical surgery? (e.g., endometrial ablation, etc.)		77%	
General Medical History (7)	History of chronic pain (e.g., fibromyalgia) (Y/N)	80%	69%
	Prior Psychiatric Disorders (e.g., Depression, Anxiety, etc.) (Y/N)	60%	69%
	Autoimmune disease (Y/N)	70%	77%
	Prior allergic or hypersensitivity reaction possibly or definitely related to materials/substances used in the index procedure (Y/N)	70%	62%
	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)		
Bleeding disorder (Y/N)	90%	100%	

PROCEDURE DATA: Index Procedure, Post-procedure Follow-up		ROUND 1 RESULTS	ROUND 2 RESULTS
General Encounter Information (16)	On what date was the index procedure performed?	100%	100%
	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.)	90%	77%
	Procedure Performed (e.g., Total Salpingectomy, Partial Salpingectomy, etc.)	100%	92%
	Facility where procedure was performed	90%	85%
	Provider ID	70%	69%
	Number of Procedures Performed by the Provider in Last Six Months (same procedure performed that was listed above)	50%	62%
	Pre-procedure imaging? (Y/N)		69%
	If yes, type of procedure? (e.g., Transvaginal Ultrasound, Hysterosalpingogram, etc.)		54%
	Inter-procedure imaging? (Y/N)		77%
If yes, type of procedure? (e.g., Transvaginal Ultrasound, Hysterosalpingogram, etc.)		62%	
Post-procedure imaging? (Y/N)	80%	92%	
If yes, type of procedure? (e.g., Transvaginal Ultrasound, Hysterosalpingogram, etc.)	80%	77%	
If yes, Post-Procedure Indication for Diagnostic Imaging (for all sterilization/LARC procedures)	50%		
If yes, were post-sterilization imaging results satisfactory for reliance on device for sterilization? (Y/N)	70%		
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)	100%	100%

Procedure Elements (Index Procedure or Follow-up) (7)	Product ID (e.g., Unique Device Identifier (UDI), National Drug Code (NDC))	80%	92%
	Placement Success Achieved (Y/N)	100%	100%
	Fallopian Tube Treated - for hysteroscopic & surgical sterilizations only (e.g., Left, Right, Bilateral)	80%	100%
	Successful Visualization of Right/Left Tubal Ostia - for hysteroscopic sterilizations only (Y/N)	80%	92%
	Primary Reason for Unsuccessful Placement (e.g., Procedure-related adverse event, poor distension, poor visualization, etc.)	80%	100%
	Intraoperative Findings - for hysteroscopic and surgical sterilizations only (e.g., Adhesions, Adnexal Mass, Fibroids, Endometriosis, etc.)	70%	92%
	Number of unsuccessful procedure attempts (for each unsuccessful attempt, specify reason)		83%
Product Removal Procedure-Specific Elements (7)	Unintended Removal by health care provider (e.g., During Dilation and Curettage, etc.)	80%	77%
	Planned Removal (Y/N)	80%	85%
	Reason for planned removal (e.g., Unable to rely on device, Pain, Bleeding, etc.)	100%	92%
	Other procedures performed with removal (e.g., Incisional Sterilization, Hysteroscopy, etc.)	80%	92%
	Complete Device Removal (e.g., Intact Device, All Fragments Removed, N/A)	90%	92%
	Partial Removal (e.g., Device Breakage Prior to Removal, etc.)	90%	92%
	Any device or implant abnormalities (Y/N)	90%	69%
MEDICATIONS (20)		ROUND 1 RESULTS	ROUND 2 RESULTS
	Pre-procedural Medication (Y/N)	88.89%	77%
	If yes, enter Medication Name (pain medication, anesthesia, etc.)		92%
	If yes, enter Indication	6.67%	77%
	If yes, enter Start Date		54%
	If yes, enter End Date		54%
	Procedural Medication (Y/N)	88.89%	85%
	If yes, enter Medication Name (pain medication, anesthesia, etc.)		92%
	If yes, enter Indication	6.67%	77%
	If yes, enter Start Date		54%
	If yes, enter End Date		54%
	Discharge Medication (Y/N)	88.89%	62%
	If yes, enter Medication Name (pain medication, anesthesia, etc.)		92%
	If yes, enter Indication	6.67%	77%
	If yes, enter Start Date		54%
	If yes, enter End Date		54%
	Follow-up Medication (Y/N)	88.89%	62%
	If yes, enter Medication Name (pain medication, anesthesia, etc.)		92%
If yes, enter Indication	6.67%	77%	
If yes, enter Start Date		54%	
If yes, enter End Date		54%	

ENDPOINTS DURING AND AFTER TREATMENT		ROUND 1 RESULTS	ROUND 2 RESULTS
Events or Complications - Permanent Hysteroscopic Sterilization (23)	Hematoma formation (Yes/No Procedure/Post-procedure Date)	70%	69%
	Device expulsion (Yes/No Procedure/Post-procedure Date)	100%	77%
	Device malposition/migration/dislocation (Yes/No Procedure/Post-procedure Date)	90%	92%
	Nerve injury (Yes/No Procedure/Post-procedure Date)	80%	69%
	Thermal injury (Yes/No Procedure/Post-procedure Date)	70%	69%
	Visceral organ injury (Yes/No Procedure/Post-procedure Date)	80%	100%
	Perforation (Yes/No Procedure/Post-procedure Date Specify Organ perforated)	100%	100%
	Vascular injury (Yes/No Procedure/Post-procedure Date)	90%	92%
	Venous thrombosis within 30 days of procedure (Yes/No Procedure/Post-procedure Date)	90%	69%
	Pulmonary Embolism within 30 days of procedure (Yes/No Procedure/Post-procedure Date)	90%	54%
	Pain requiring prescriptive medication (Yes/No Procedure/Post-procedure Date)	90%	77%
	Vasovagal syncope or seizure on day of placement (Yes/No Procedure/Post-procedure Date)	70%	62%
	Pelvic inflammatory disease (PID) (Yes/No Procedure/Post-procedure Date)	90%	69%
	Other Infection (Yes/No Procedure/Post-procedure Date)	90%	54%
	Anesthesia-related event (Yes/No Procedure/Post-procedure Date)	80%	85%
	Inability to access fallopian tubes during procedure (Yes/No)	70%	77%
	Nausea or vomiting (Yes/No Procedure/Post-procedure Date)	60%	62%
	Fainting or dizziness (Yes/No Procedure/Post-procedure Date)	50%	62%
	Surgical hemorrhage (Yes/No)	90%	85%
	Other medical product related adverse event (AE) (Yes/No Procedure/Post-procedure Date)	80%	62%
	If yes, specify		54%
	Other procedure related (Yes/No Procedure/Post-procedure Date)		69%
	If yes, specify		62%

Events or Complications – All Other Permanent Surgical Sterilization (24)	Hematoma formation (Yes/No Procedure/Post-procedure Date)	70%	77%
	Device expulsion (Yes/No Procedure/Post-procedure Date)	100%	69%
	Device malposition/migration/dislocation (Yes/No Procedure/Post-procedure Date)	90%	77%
	Nerve injury (Yes/No Procedure/Post-procedure Date)	80%	85%
	Thermal injury (Yes/No Procedure/Post-procedure Date)	70%	85%
	Visceral organ injury (Yes/No Procedure/Post-procedure Date)	80%	92%
	Perforation (Yes/No Procedure/Post-procedure Date Specify Organ perforated)	100%	77%
	Vascular injury (Yes/No Procedure/Post-procedure Date)	90%	92%
	Venous thrombosis within 30 days of procedure (Yes/No Procedure/Post-procedure Date)	90%	69%
	Pulmonary Embolism within 30 days of procedure (Yes/No Procedure/Post-procedure Date)	90%	54%
	Pain requiring prescriptive medication (Yes/No Procedure/Post-procedure Date)	90%	77%
	Vasovagal syncope or seizure on day of placement (Yes/No Procedure/Post-procedure Date)	70%	62%
	Subcutaneous emphysema (Yes/No Procedure/Post-procedure Date)	60%	69%
	Pelvic inflammatory disease (PID) (Yes/No Procedure/Post-procedure Date)	90%	77%
	Other Infection (Yes/No Procedure/Post-procedure Date)	90%	77%
	Anesthesia-related event (Yes/No Procedure/Post-procedure Date)	80%	85%
	Inability to access fallopian tubes during procedure (Yes/No)	70%	77%
	Nausea or vomiting (Yes/No Procedure/Post-procedure Date)	60%	54%
	Fainting or dizziness (Yes/No Procedure/Post-procedure Date)	50%	54%
	Surgical hemorrhage (Yes/No)	90%	100%
	Other medical product related AE (Yes/No Procedure/Post-procedure Date) If yes, specify	80%	69%
	Other procedure related AE (Yes/No Procedure/Post-procedure Date) If yes, specify		62%
			69%
			62%
Events or Complications – LARC – Contraceptive Implants (15)	Hematoma formation (Yes/No Procedure/Post-procedure Date)	70%	85%
	Device expulsion (Yes/No Procedure/Post-procedure Date)	100%	69%
	Device malposition/migration/dislocation (Yes/No Procedure/Post-procedure Date)	90%	85%
	Nerve injury (Yes/No Procedure/Post-procedure Date)	80%	85%
	Vascular injury (Yes/No Procedure/Post-procedure Date)	90%	85%
	Venous thrombosis within 30 days of procedure (Yes/No Procedure/Post-procedure Date)	90%	54%
	Pain requiring prescription medication (Yes/No Procedure/Post-procedure Date)	90%	54%
	Deep placement of implant (Yes/No Procedure/Post-procedure Date)	90%	92%
	Other Infection (Yes/No Procedure/Post-procedure Date)	90%	77%
	Fainting or dizziness (Yes/No Procedure/Post-procedure Date)	50%	54%
	Surgical hemorrhage (Yes/No)	90%	54%
	Other medical product related AE (Yes/No Procedure/Post-procedure Date) If yes, specify	80%	69%
	Other procedure related AE (Yes/No Procedure/Post-procedure Date) If yes, specify		54%
			69%
			54%

Events or Complications – LARC – Intrauterine Devices (18)	Hematoma formation (Yes/No Procedure/Post-procedure Date)	70%	54%
	Device expulsion (Yes/No Procedure/Post-procedure Date)	100%	100%
	Device malposition/migration/dislocation (Yes/No Procedure/Post-procedure Date)	90%	100%
	Nerve injury (Yes/No Procedure/Post-procedure Date)	80%	54%
	Visceral organ injury (Yes/No Procedure/Post-procedure Date)	80%	77%
	Perforation (Yes/No Procedure/Post-procedure Date Specify Organ perforated)	100%	100%
	Vascular injury (Yes/No Procedure/Post-procedure Date)	90%	62%
	Venous thrombosis within 30 days of procedure (Yes/No Procedure/Post-procedure Date)	90%	54%
	Pain requiring prescription medication (Yes/No Procedure/Post-procedure Date)	90%	77%
	Vasovagal syncope or seizure on day of placement (Yes/No Procedure/Post-procedure Date)	70%	69%
	Pelvic inflammatory disease (PID) (Yes/No Procedure/Post-procedure Date)	90%	92%
	Other Infection (Yes/No Procedure/Post-procedure Date)	90%	69%
	Nausea or vomiting (Yes/No Procedure/Post-procedure Date)	60%	54%
	Fainting or dizziness (Yes/No Procedure/Post-procedure Date)	50%	54%
	Other medical product related AE (Yes/No Procedure/Post-procedure Date)	80%	62%
	If yes, specify		54%
	Other procedure related AE (Yes/No Procedure/Post-procedure Date)		62%
If yes, specify		54%	
Pregnancy (20)	Date of confirmation of pregnancy	90%	100%
	Gestational age at presentation (in weeks)		100%
	Estimated due date (relatively easy to calculate and can be done at the time of presentation)	60%	62%
	Pregnancy outcome	90%	100%
	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		100%
	If yes, type (select from following options)		100%
	Termination of pregnancy		100%
	If yes, trimester (first, second, third)		100%
	Miscarriage/fetal demise (e.g. Intra Uterine Fetal Death (IUFD))	88.89%	100%
If yes, trimester (first, second, third)		100%	
Other abnormal pregnancy (e.g. molar)			
If yes, trimester (first, second, third)			
Delivery	77.78%	100%	
If yes, choose preterm or term	88.89%	100%	
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)	100%	100%
	Outcome of Treatment of AE (e.g., Recovered, Recovered with Unresolved Sequelae, etc.)	90%	100%