Registry Protocol–**Research Registry (PFDR-R)**

Version 1.3
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List of Abbreviations

ACOG	American Congress of Obstetrics and Gynecology
AE	Adverse event
AUA	American Urologic Association
AUGS	American Urogynecologic Society
BMI	Body mass index
CFR	Code of Federal Regulations
CMS	Centers for Medicaid and Medicare Services
CRF	Case report form
eCRF	Electronic case report form
EDC	Electronic data capture
HRT	Hormone replacement therapy
ICIQ-UI SF	International Consultation on Incontinence Questionnaire- Urinary Incontinence – Short Form
ICU	Intensive Care Unit
FDA	U.S. Food and Drug Administration
FI	Fecal incontinence
FPMRS	Female Pelvic Medicine and Reconstructive Surgery
HIPAA	Health Insurance Portability and Accountability Act
MAUDE	Manufacturer and User Device Experience database (FDA)
MDR	Medical device report
MMK	Marshall Marchetti Krantz procedure
OR	Operating room
PFD	Pelvic floor disorder
PFDR	Pelvic Floor Disorders Registry
PFDR- IS	Pelvic Floor Disorders Registry -
PFDR-R	PFDR - Research
PFDI-20	Pelvic Floor Distress Inventory – 20 Item Short Form
PFIQ-7	Pelvic Floor Impact Questionnaire – 7 Item Short Form
PGI-I	Patient Global Impression of Improvement
PHN	Public health notification
PISQ-12	Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire – 12 Item Short Form
PME	Pelvic muscle exercise
POP	Pelvic organ prolapse
POP-Q	Pelvic Organ Prolapse Quantification system
PQRS	Physician Quality and Reporting Systems
PRO	Patient-reported outcome
RCT	Randomized controlled trial
RSC	Registry Steering Committee
QoL	Quality of life
SAP	Statistical analysis plan
SUI	Stress urinary incontinence
SUFU	Society for Urodynamics and Female Pelvic Medicine and Urogenital Reconstruction
UDS	Urodynamics
UI	Urinary incontinence

applicable, subject to reporting requirements of the FDA. At the conclusion of industry-sponsored 522 studies, the AUGS Research Registry Committee may perform secondary analyses of the Industry Sponsored Research Registry subject to the restrictions of the data use agreements outlined between AUGS and the industry sponsor.

5.2 Missing Data

Full details on handling of all missing data, which are common in observational studies, will be described separately in the SAP. In general, missing data will not be imputed and the data will be analyzed as they are recorded in the registry electronic case report forms (eCRFs).

5.3 Data Reporting

The main findings of the PFDR will be reported in a Registry Report at least annually and posted on the PFD Registry website. Status (e.g., enrollment statistics) and benchmarking reports will be provided periodically to participating sites and stakeholders. Following approach outlined in 5.1, Registry Reports will present aggregate efficacy and safety data for the following categories of surgical procedures: 1) Transvaginal Native Tissue; 2) Transvaginal Mesh Procedures – Permanent Synthetic; 3) Transvaginal Mesh Procedures - Biologic; 4) Sacrocolpopexy and 5) Obliterative Repairs and one non-surgical category: Pessary. Within each surgical category, data will be presented by anatomic prolapse compartment at enrollment: Anterior, Posterior, Apical (Table 2). Data from the Industry Sponsored Research Registry may be incorporated, at the discretion of the AUGS Registry Scientific and Steering Committees, into the aggregate data depending upon the data use agreements outlined between AUGS and Industry sponsor; any such addition will be clearly labeled.
Registry report Efficacy data included in the Registry Reports will include the Primary Effectiveness Endpoints (Section 4.4.3) and Secondary Efficacy and Quality of Life endpoints (Section 4.4.4) Only patients with a minimum of 12 months of follow-up after their index surgery will be included in Efficacy data in the Registry Report. Safety data will include the Primary Safety Endpoints outlined in 4.4.5 and Appendix A. Additional ancillary analyses may be reported on an ad hoc basis (See Section 6.7). At the participant's request, select measures may be reported to the Center for Medicare & Medicaid Services (CMS) to fulfill requirements for Physician Quality Reporting System (PQRS).

6. Registry Conduct

6.1 Governance

Registry Steering Committee – The work of the Registry will be guided by a Registry Steering Committee (RSC). This committee will be responsible for developing and implementing the strategic goals of the registry and is the governing body that oversees registry operations; including the successful implementation, monitoring and management of resources and activities. Please see Registry Steering Committee Charter available at http://pfdregistry.augs.org/governance.

Stakeholder Advisory Board – PFD Registry Stakeholder Advisory Board serves as the vehicle for key partners to support and provide input to the AUGS PFD Registry and to support and conduct clinical research and improve quality of care for women with PFD. See Stakeholder Advisory Board Charter available at http://pfdregistry.augs.org/governance.

Additional Committees – The Registry Steering Committee has the ability to designate committees or working groups to advance the work of the Registry and report back to the Steering Committee. Current Committees include, but are not limited to:

- *Research Registry Committee*. This Committee is responsible for overseeing the scientific content of the registry including data elements, design and implementation. The chair of the Scientific Committee is appointed by the AUGS Board of Directors for a three-year term. A broad group of urogynecologists, gynecologists, urologists and other relevant disciplines will be appointed to this committee by the Chair of Scientific Committee to ensure the Registry is responsive to the needs of physicians treating patients with PFD. This Committee also will review requests for data use and analysis. This Committee will develop additional sub-committees to assist in ensuring the scientific integrity of the Registry (e.g. Publications, Quality, Website) as needed.

Conflicts of Interest – Conflicts of interest (COI) shall be disclosed annually, via completion of the AUGS COI form, and then reviewed by the AUGS Governance Committee per AUGS policy. Members of the Research Registry Committee and the Chair and Vice Chair of the RSC must be free of relevant financial conflict of interest during their time of service on these committees. Other AUGS officers and members must comply with the AUGS conflict of interest policy (available at http://www.augs.org/p/cm/ld/fid=4).

6.2 Data Entry/Electronic Data Capture

All data will be collected and entered directly into the Quintiles | Outcome electronic data capture (EDC) system. Some patient-reported data may be collected on paper and entered into the registry by PFDR or site staff. Remote training for data entry procedures will be provided. All participating sites will have access to the data entered regarding the individual site's own enrolled patients. All sites will be fully trained on using the on-line data capture system, including eCRF completion guidelines and help files. Sites will be responsible for entering patient data into a secure internet-based EDC registry database via the eCRF. Providers and site personnel will be able to access their account with a username and password. A project-specific email address will be provided on the registry website portal page for use by anyone interested in participating in the registry or receiving more information about the registry. In addition, for registered users, Help Desk support is available for issues related to the registry and data collection. The Help Desk team is equipped to handle any operational or logistical questions.

All eCRFs should be completed by designated, trained personnel or a study coordinator, as appropriate. All changes or corrections to eCRFs will be documented in an automated audit trail and an adequate explanation is required.

6.3 File Retention and Archiving

The site agrees to keep relevant registry records, including the identity of all participating patients and all original signed informed consent forms (as applicable).

Studies conducted as part of the Industry Sponsored Research Registry participation may entail additional file retention specifications, which will be described in individual study protocols. In general, study records for Industry sponsored studies (e.g., original signed informed consent forms, source documents)

should be retained by the site according to local regulations, or as specified in the study contract, whichever is longer. In the event that archiving of the file is no longer possible at the site, the site will be instructed to notify the study sponsor.

6.4 Quality Assurance

The database will be housed by Quintiles | Outcome in a physically and logically secure computer system maintained by Quintiles | Outcome in accordance with a written security policy. The system meets the standards of the International Committee on Harmonization (ICH) guideline E6R1 regarding electronic data handling and is available for audit upon request. The system also meets approved U.S. federal standards for the security of health information and is validated.

Due to the nature of the registry, it is anticipated that the majority of quality controls will be implemented through edit checks and data queries issued through the EDC system.

6.5 Data Management

A data management plan will be created before data collection begins and will describe all functions, processes, and specifications for data collection, cleaning and validation. The eCRFs will include programmable edits to obtain immediate feedback if data are missing, out of range, illogical or potentially erroneous. Concurrent manual data review will be performed based on parameters dictated by the plan. Ad hoc queries may be generated within the EDC system and followed up for resolution.

High data quality standards will be maintained and processes and procedures utilised to repeatedly ensure that the data are as clean and accurate as possible when presented for analysis.

6.6 Protocol Amendments

Any changes in protocol will be reviewed and approved by the RSC. Changes to the protocol will be documented in written protocol amendments and the Stakeholder Advisory Board will be notified prior to implementation. No changes or amendments to this protocol may be made by the participating providers or other stakeholders unless such change(s) or amendment(s) has/have been fully discussed and approved by the RSC.

6.7 Requests for Ancillary Data Analyses

The RSC (described in Section 6.1) will develop written policies, for access and utilization of registry-generated data. Data analysis results may be requested for abstract submission to scientific meetings, development of manuscripts for peer-review journal submission, and scientific symposia. The Research Registry Committee also works with the RSC to ensure appropriate dissemination of treatment-related and clinical course related information to health authorities and stakeholders. These roles and policies will be codified in the committee charters.
The PFDR-R Registry will be used for research. Research will generally be

performed using PFDR-R data, because patients enrolled in the PFDR-R have provided informed consent for their participation. The Research Registry also has other advantages as a source of research data, including 1) more detailed data collection, 2) patient-reported quality of life and other outcomes, 3) nonsurgical (pessary) treatment outcomes and 4) likely more complete follow-up or longitudinal data.

Participating PFDR-R sites may publish or present the results of their own data and will be granted publication priority by the Publications Subcommittee for data solely originating from their site. Individual considerations for data access and use will not hinder the publication of full aggregate data analyses or registry results. The Research Registry Committee will meet at regular intervals to review incoming proposals for consolidated data analyses from any source, including financial sponsors of the registry, submitted via a common form comprised of information regarding the scientific basis for the proposal, the data required, the methods to be utilized in the analysis, the likely significance of the results and the proposed plan for publication or other dissemination of the registry results. The Research Registry Committee will provide recommendations to the RSC that include an assessment of the scientific validity of the proposal as well as its ranked priority for implementation.

6.8 Publication Policy

Any publication of the results from this registry must be consistent with the PFDR publication policy and guided by the Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication of the International Committee of Medical Journal Editors (ICMJE), updated April 2010.

Completed manuscripts involving data from more than one registry site must be provided to the Publications Sub-committee for review and comment, ideally, at least thirty (30) days prior to submission or presentation.

7. Safety Reporting

7.1 Definitions

Adverse Event
An ***adverse event*** (AE) is any symptom, sign, illness or experience that develops or worsens in severity during the course of the registry. Intercurrent illnesses or injuries should be regarded as AEs.

Serious injury
Any injury or illness during the course of the registry that is any one of the following:

- life-threatening
- results in permanent impairment of a body function or permanent damage to body structure

- necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure

See Appendix for definitions of adverse events and other clinically important events.

7.2 Reporting to the FDA

User facilities are required to report suspected medical device related deaths to both the FDA and the manufacturers within 10 days of learning of its occurrence. User facilities are required to report medical device related serious injuries to the manufacturer only within 10 days of learning of its occurrence. If the medical device manufacturer is unknown, the serious injury is reported by the facility to FDA. Manufacturers have 30 days to report medical device related deaths and serious injuries to FDA, and 5 days to report events that require remedial action to prevent an unreasonable risk of substantial harm to the public health. All regulatory reporting for events reported in the PFDR-R remain the responsibility of the user facility.

8. Ethical and Regulatory Considerations

8.1 Guiding Principles

The study will be conducted in compliance with the US FDA Title 21 CFR Part 50 – Protection of Human Patients and/or Part 56 – Institutional Review Boards; the International Conference on Harmonization (ICH) GCP guidelines (May 9, 1997) as they apply to post-market, observational studies; the Declaration of Helsinki and its amendments; and the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

8.2 Risks and Benefits of Patient Participation

Patient participation in the registry is considered of minimal risk. One potential risk is associated with the inadvertent release of personal medical data; however, every possible safeguard will be enacted during the conduct of this registry to prevent any breech of patient confidentiality from occurring (refer to Section 8.4).

One of the main purposes of the registry is to generate balanced evidence regarding treatments for PFD and improve patient outcomes. Patients that participate in the registry may not receive direct benefit, but the knowledge gained regarding comparative treatment outcomes could result in optimization of their future care as well as the care of other patients with PFD.

8.3 Patient Information and Informed Consent

An informed consent form (ICF) must be signed by the patient (or the patient's legally authorized representative) before her participation and enrollment in the Research Registry. All patients will complete a HIPAA authorization prior to enrollment. The medical file for each patient should document the informed consent process and that written informed consent was obtained prior to

participation in the study. A copy of each signed ICF must be provided to the patient or the patient's legally authorized representative. All signed and dated ICFs must remain in each patient's study file. A registry-specific ICF (and HIPAA Authorization for Release of Information) template will be provided to sites to facilitate the submission process.

The ICF should be revised whenever there are changes to procedures outlined in the informed consent or when new information becomes available that may affect the willingness of the patient to participate. For any updated or revised ICFs, the medical file for each patient should document the informed consent process and that written informed consent was obtained for the updated/revised ICF for continued participation in the study. Documentation of appropriate informed consent is subject to audit.

8.4 Patient Confidentiality

In order to maintain patient confidentiality, each patient will be assigned a unique patient identifier upon registry enrollment. This patient identifier will be used in place of patient name for the purpose of data analysis and reporting. Medical record number or other local reference identifiers are not collected as part of the database. All parties will ensure protection of patient personal data and will not include patient names on any forms, reports, publications, or in any other disclosures, except where required by law. Patients will be informed about data handling procedures and asked for their consent at sites participating in the PFDR-R. Data protection and privacy regulations will be observed in capturing, forwarding, processing, and storing patient data. Patient confidentiality will be strictly maintained.

8.5 Institutional Review Board

Consistent with local regulations and prior to enrollment of patients at a given site, the PFDR-R registry protocol will be submitted together with its associated documents (e.g., ICF) to the responsible central and/or local IRB for its review, as required. Patient enrollment will not start at any site before the registry has obtained written confirmation of a favorable opinion/approval from the relevant central or local IRB. The IRB will be asked to provide documentation of the date of the meeting at which the favorable opinion/approval was given that clearly identifies the registry, the protocol version, and the ICF version reviewed.

Before implementation of any substantial changes to the protocol, protocol amendments will also be submitted to the relevant IRB in a manner consistent with local regulations. Pertinent safety information will be submitted to the relevant IRBs during the course of the registry in accordance with local requirements. It is the responsibility of the site to have prospective approval of the registry protocol, protocol amendments, and informed consent forms, and other relevant documents, if applicable, from their local IRB and provide documentation of approval to the registry.

8.6 Separation of Industry-Sponsored Data

The credibility and integrity of the data and reports associated with the PFDR require that the Registry be free of commercial bias and influence. There is a common understanding that all governing policies are transparent and developed using an independent process, based on the best scientific evidence. One of the primary objectives of the PFDR is to provide a platform for industry sponsored studies required to fulfill the FDA's request for post-market surveillance for transvaginal mesh for POP and, in the future, potentially other surgical devices. In so much as industry sponsorship has the potential to create real or

perceived conflicts of interest with the PFDR as a whole or its other objectives, clear policies have been instituted to minimize this conflict and preserve the integrity, credibility and independence of the PFDR. The AUGS conflict of interest policy (available at http://www.augs.org/d/do/691) serves as the guiding document in this process (see also Section 6.1 Governance above). Data from industry-sponsored studies, including the 522 postmarketing surveillance studies, will be captured exclusively in the Industry Sponsored Research Registry. Industry-sponsored data will be kept distinct and separate from the Research Registry, with each individual industry-sponsored study collecting data in its own independent (and secure) "protocol" within the EDC. Participation in the Research Registry (PFDR-R) will be voluntary; sponsorship by a medical device company or other commercial interest is strictly prohibited. Only data submitted by surgeons or sites into the Research Registry will be used for an individual surgeon's or site's quality improvement activities or maintenance of certification, should the PFDR be approved for these purposes in the future. Data reporting and analyses from the Research Registry will be performed under strict guidance of the PFDR Scientific Committee independent of industry influence. All Registry Scientific Committee members must be free of relevant conflicts of interest. The RSC will be responsible for ensuring that transparent processes exist for access, use, analyses and publication of data from the PFDR. Corporate Sponsors will not be allowed to participate in the direct management of the PFDR and individuals who are employed by or engaged to represent a Sponsoring Company are not eligible to serve on the Registry Scientific Committee or serve as an expert advisor or reviewer on behalf of the Registry. As members of the PFDR Stakeholder Advisory Board, industry sponsors may request analyses of data from the Research Registry, subject to approval of the RSC and conducted by the Registry Scientific Committee.

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Appendix : Adverse Event (AE) and Related Clinically Important Event Definitions*

	Event	Definition/Data Collected
Intraoperative complications	Bleeding requiring blood transfusion	yes/no, # of units of packed red blood cells
	Visceral organ injury (proctotomy, enterotomy, cystotomy)	Injury to the rectum, large intestine, small intestine, or bladder
	Vascular injury	Injury to a major blood vessel, diagnosed by imaging study or surgical intervention
	Ureteral kink/injury	Failure of one or both ureters to adequately deliver urine to the bladder, as determined either intra- or post-operatively. Management: a) Suture removed, ureteral kinking released without further intervention; b) Ureteral stent placed; c) Primary reanastomosis of transected ureter; d) Reimplanation; e) Percutaneous nephrostomy; f) Nephrectomy
	Urethrotomy	Unplanned piercing or creation of an opening in the urethra, recognized intraoperatively
	Aborted procedure due to intraoperative event*	Surgical procedure aborted due to an interaoprative event
	Mesh kit/device malfunction*	Any abnormal occurrence attributable specifically to the components of the mesh kit before or during placement, i.e. trocar releases from mesh material, abnormality of the protective sleeve surrounding the mesh material, etc. Recognized intraoperatively
Postoperative complications (occurring ≤12 weeks after index surgery only)	Ileus/bowel obstruction	Hypomotility, or partial or complete blockage of the GI tract associated with nausea or vomiting based on clinical or radiographic criteria
	Thrombotic events	Formation of a blood clot (thrombus) in an artery or vein requiring anticoagulation therapy. A thrombus can block blood flow at the point of clot formation or break free to block it elsewhere (embolism). Does not include prophylactic therapy
	Severe or acute cardiac events (e.g., myocardial infarction)	Any severe or acute cardiovascular condition including acute MI, unstable angina or cardiac mortality.
	Pulmonary Event	Pulmonary edema or pneumonia
	Cerebrovascular events	Cerebrovascular event
	Intensive care unit (ICU) admission*	Any unplanned admission to an intensive care unit
	Return to operating room (OR) to manage a complication during index hospitalization*	Return to operating room (OR) during the index hospitalization to manage a complication
Postoperative complications	Lower urinary tract infection	Urinary tract infection (UTI) based on clinical judgment or confirmation of a culture proven by lab criteria also includes empiric antibiotic treatment for symptoms thought to be secondary to UTI
	Infection of bone	Infection and noninfectious inflammation of

(occurring at any time point after surgery through 36 months)		the bone and surrounding muscles (e.g. pubic symphysis (osteitis pubis), sacrum (sacral osteomyelitis), or other bony structure)
	Vaginal infection	Infection of the vagina determined by a physician using clinical or radiologic indicators to be uncommon to vagina and requiring treatment
	Pelvic infection or abscess	Infection/cellulitis of the pelvic organs determined by physician using clinical or radiologic indicators and requiring treatment
	Other infection	Infection diagnosed using clinical or radiologic indicators not including vaginal infection, lower urinary tract infection, pelvic infection/abscess or infection/inflammation of bone
	Atypical vaginal discharge	New onset of vaginal discharge not suggestive of typical, common vaginitis
	Vaginal wall dehiscence	Separation of the vaginal tissue layers at the surgical site incision
	Vaginal scarring	De novo vaginal scar requiring medical or surgical intervention, or adversely affecting quality of life
	Vaginal shortening	A clinically significant decrease in total vaginal length requiring medical or surgical intervention, or adversely affecting patient quality of life
	Mesh exposure into vagina	The observation of mesh through the vaginal wall or epithelium. This condition is synonymous with mesh extrusion. Location (anterior, posterior, distal vagina/introitus, apex)
	Mesh erosion into viscera	Perforation of mesh into a hollow organ or viscus. Location (urethra, bladder, ureter, rectum, bowel - all that apply)
	Suture exposure in vagina	The observation of suture through the vaginal wall or epithelium. This condition is synonymous with suture extrusion. Location (anterior, posterior, distal vagina/introitus, apex)
	Suture erosion into viscera	Perforation of suture into a hollow organ or viscus. Location (urethra, bladder, ureter, rectum, bowel - all that apply)
	Neuromuscular disorder (including groin and leg pain)	A disorder or range of conditions associated with the dysfunction of nerves and/or muscles leading to pain, sensory loss, weakness or immobility. This would include groin and leg pain
	Pelvic pain (beyond 12 weeks post-surgery)	Any pain associated with worsening bother compared to preop occurring in the lower abdomen or genital area beyond 12 weeks post-operatively (excluding neuromuscular pain and dyspareunia)
	De novo vaginal bleeding (beyond 6 weeks	New onset or persistent vaginal bleeding

Postoperative complications (continued) [occurring at any time point after surgery through 36 months]	post-surgery)	beyond 6 weeks
	De novo or worsening dyspareunia	De novo: Any new onset pain associated with sexual activity that was not present during sexual activity preoperatively. Worsening: Any worsening pain associated with sexual activity compared to preoperative state. (Any incremental worsening compared to preop; does NOT include De Novo Dyspareunia)
	Fistula	An abnormal connection between two epithelium-lined organs that do not normally connect including vesicovaginal, rectovaginal, ureterovaginal, urethrovaginal, enterovaginal/colovaginal, enterovescial
	Sinus tract	A pathologic communication between a body cavity and an adjoining space (e.g. between vagina and peritoneal cavity through which fluid can drain)
	Hematoma	A localized swelling filled with blood resulting from a break in a blood vessel (abdominal, retroperitoneal, retropubic, obturator, vaginal, mons, other.)
	New or worsening voiding dysfunction	The new onset or worsening inability to completely empty the bladder during urination.
	New or worsening stress incontinence	The new onset or worsening involuntary loss of urine during period of increased abdominal pressure. Such events include laughing, sneezing, coughing or lifting heavy objects.
	New or worsening urge incontinence	The new onset or worsening involuntary loss of urine occurring for no apparent reason while suddenly feeling the need or urge to urinate.
	New or worsening constipation	New onset or worsening condition in which bowel movements occur less often than 3 times per week (NIDDK).
	New or worsening fecal incontinence	New onset or worsening uncontrolled loss of gas or stool (feces) through the anus.
	Hospital re-admission related to index surgery*	Any unplanned admission within 3 years of index surgery
	Re-operation to manage postoperative complications including mesh complication*	Any return to the operating room for complication, recurrent POP or new onset symptom such as SUI
	Death	

Events labeled with a (*) are clinically important events that are not strictly defined as AEs but are related and/or the secondary result of an adverse event that will be captured and reported by the registry.