



## LIMITED GUARANTEE FOR MESH PELVIC RECONSTRUCTIVE SURGERY

### TERMS AND CONDITIONS

- Mesh Pelvic Reconstructive Surgery Care Plan.** Saint Luke's Hospital of Bethlehem, Pennsylvania d/b/a St. Luke's Hospital & Health Network ("St. Luke's") and The Institute for Female Pelvic Medicine & Reconstructive Surgery ("IFPM") have developed and implemented at St. Luke's a multi-faceted care plan (the "Mesh Pelvic Reconstructive Surgery Care Plan") to direct the pre-operative and inpatient process for patients who undergo pelvic reconstructive surgery utilizing mesh (the "Surgery") at St. Luke's performed by physicians employed by IFPM. The Mesh Pelvic Reconstructive Surgery Care Plan is intended to optimize a patient's chances for a successful Surgery.
- Non-Reimbursable Events.** In addition to the development and implementation at St. Luke's of the Mesh Pelvic Reconstructive Surgery Care Plan, St. Luke's and IFPM have identified the following three specific events which should typically be preventable during the Surgery: (a) rectal injury requiring fecal diversion and/or additional procedures related to rectal injury; (b) urethral injury that is not repaired during the Surgery; and (c) prolonged voiding dysfunction requiring retention of a foley catheter by a patient for more than thirty (30) days following the date the patient undergoes the Surgery (the "Non-Reimbursable Events").
- Non-Reimbursable Readmission.** A "Non-Reimbursable Readmission" means readmission to St. Luke's within thirty (30) days following the date a patient undergoes the Surgery at St. Luke's as a direct result of an adverse outcome caused solely by an urogynecologist's technical portion of the Surgery performed at St. Luke's. A Non-Reimbursable Readmission does not include a readmission caused by an adverse outcome if the adverse outcome is not caused solely by an urogynecologist's technical portion of the Surgery. For example, if a patient experiences an adverse outcome associated with the use of the graft insertion (mesh) requiring mesh revision, or infection, erosion, chronic inflammation, acute or chronic pain, pain with intercourse, fistula, disturbance in bowel or bladder function, or if a patient experiences other adverse outcomes unrelated to the mesh insertion, such as a heart attack, stroke or pulmonary embolism during or following the Surgery requiring readmission, the adverse outcome would not be caused solely by an urogynecologist's technical portion of the Surgery and thus the adverse outcome resulting in the readmission would not be a Non-Reimbursable Event. The adverse events listed in the prior sentence are only examples and are not intended to include all adverse events not caused solely by an urogynecologist's technical portion of the Surgery.
- Limited Guarantee.** If St. Luke's or IFPM fails to follow the Mesh Pelvic Reconstructive Surgery Care Plan with regard to an eligible patient, or if an eligible patient experiences a Non-Reimbursable Event or a Non-Reimbursable Readmission, then St. Luke's and IFPM agree to refrain from billing the eligible patient or her insurance company (if applicable) for any charges associated with the Surgery or the Non-Reimbursable Readmission.
- Eligible Patients.** The limited guarantee applies only to patients (a) of IFPM; (b) who have had no prior reconstructive pelvic surgery; (c) who do not have at the time of Surgery neurological disease that adversely impacts bladder function; (d) who undergo Surgery at St. Luke's; (e) who sign the patient acknowledgment described below; and (f) with respect to patients who experience a Non-Reimbursable Readmission, who are readmitted to St. Luke's for the Non-Reimbursable Readmission. IFPM will notify a patient prior to Surgery if the patient has a co-morbidity factor which makes the patient ineligible to participate in the limited guarantee. IFPM currently includes only the following physicians: Vincent Lucente, M.D., Miles Murphy, M.D., Nazanin Ehsani, M.D. and Heather vanRaalte, M.D. However, IFPM may hire or engage additional physicians from time to time.

Also, the above named physicians may cease practicing through IFPM. Accordingly, the patient should confirm that her physician is employed or engaged through IFPM at the time of Surgery to ensure that the limited guarantee applies. If a patient undergoes a pelvic reconstructive surgery utilizing mesh with any other physician, if a patient undergoes a pelvic reconstructive surgery utilizing mesh at a hospital other than St. Luke's, or if a patient is admitted to a hospital other than St. Luke's for any adverse outcome which might otherwise be a Non-Reimbursable Readmission, she is not eligible to participate in the limited guarantee.

6. **No Limited Guarantee for Materials.** Pelvic reconstructive surgery utilizing mesh typically involves the placement of synthetic mesh through small incisions to provide durable support for pelvic organs. The limited guarantee does not apply to the surgical mesh inserted during the Surgery. For example, the limited guarantee would not apply if the surgical mesh erodes or if other complications develop from the mesh insertion. Each patient is given a copy of the labeling from the surgical mesh manufacturer prior to Surgery. The labeling includes important information concerning certain risks the patient assumes in connection with the mesh placement. The limited guarantee does not apply to adverse outcomes associated with the mesh itself.

7. **FDA Notification.** The U.S. Food and Drug Administration (FDA) issued an alert on October 20, 2008 relating to serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence, which each patient contemplating the Surgery should read. Prior to undergoing the Surgery, each patient must acknowledge that she was advised of the FDA alert. In addition, IFPM issued a position paper in response to the FDA alert, which is available from IFPM to patients contemplating the Surgery upon request to IFPM.

8. **Patient Acknowledgement.** In order to be eligible for the limited guarantee, a patient must execute prior to the Surgery a patient acknowledgement in the form delivered by IFPM. The patient acknowledgement includes a verification by the patient that certain portions of the Mesh Pelvic Reconstructive Surgery Care Plan have been performed, such as a discussion between the physician and the patient concerning other treatment options. The patient must also agree to follow her pre- and post-surgical instructions.

9. **Other Professional Services.** Certain third parties other than St. Luke's and IFPM, including certain affiliates of St. Luke's, may provide services in connection with a Surgery performed at St. Luke's, the treatment of a Non-Reimbursable Event or treatment provided during a Non-Reimbursable Readmission. For example, an anesthesiologist may provide and bill for professional services performed in connection with the Surgery or a cardiologist may provide consultative services during a patient's recovery at St. Luke's. The limited guarantee is not intended to, and does not, preclude these professionals from billing a patient for services provided, including such professionals employed or engaged by St. Luke's or its affiliates.

10. **Requests for Payments.** If an eligible patient believes that St. Luke's or IFPM failed to follow the Mesh Pelvic Reconstructive Surgery Care Plan with regard to her Surgery or if an eligible patient experiences a Non-Reimbursable Event or a Non-Reimbursable Readmission, the patient must deliver written notice to IFPM within ninety (90) days following the date of the Surgery at the following address:

**The Institute for Female Pelvic Medicine  
& Reconstructive Surgery  
2200 W. Hamilton Street, Suite 111  
Allentown, PA 18104  
Attn: Kimberly Pammer**

A patient must provide a detailed written description of the failure to comply with the Mesh Pelvic Reconstructive Surgery Care Plan, the Non-Reimbursable Event that transpired or the adverse outcome caused solely by an urogynecologist's technical portion of the Surgery that led to a Non-Reimbursable Readmission. If requested by IFPM, the patient shall submit to one (1) or more physical examinations by a physician employed or engaged by IFPM, so that the physician may adequately evaluate the patient and determine whether the limited guarantee applies.

11. **Purposes of the Limited Guarantee.** The Mesh Pelvic Reconstructive Surgery Care Plan is designed to improve patient outcomes, and the limited guarantee is intended to demonstrate the desire of St. Luke's and IFPM to follow certain practices and procedures in furtherance thereof. However, St. Luke's and IFPM cannot guarantee specific outcomes for patients. For example, the Non-Reimbursable Events are atypical, but they may occur from time to time. In addition, any failure to follow the Mesh Pelvic Reconstructive Surgery Care Plan or the occurrence of a Non-Reimbursable Event or a Non-Reimbursable Readmission is not intended to constitute an acknowledgement of fault or wrongdoing by St. Luke's, IFPM or IFPM's physicians and shall not be deemed to be an admission of liability by St. Luke's, IFPM or IFPM's physicians. Further, this document and its terms and conditions shall not be used as evidence in any legal proceeding alleging professional negligence or misconduct, nor shall the fact that an event defined as a "Non-Reimbursable Event" occurred be competent evidence in any such proceeding. The standards set forth in the limited guarantee may be a higher standard than the applicable standard of care required by law.

12. **Terms May Change.** The terms of the limited guarantee, including the elements of the Mesh Pelvic Reconstructive Surgery Care Plan, the specified Non-Reimbursable Events and/or the definition of a Non-Reimbursable Readmission, may change from time to time. Patients should revisit these terms and conditions prior to undergoing the Surgery. The latest terms and conditions and Mesh Pelvic Reconstructive Surgery Care Plan posted at <http://www.mystlukesonline.org/pelvic-surgery/index.aspx> at least five (5) days prior to the date of Surgery shall apply to a patient.

13. **Patients Scheduled On or Prior to July 15, 2009.** A patient who undergoes the Surgery at St. Luke's on or prior to July 15, 2009 is not eligible to participate in the limited guarantee. An eligible patient scheduled prior to July 15, 2009 for the Surgery but who undergoes the Surgery after July 15, 2009 may participate in the limited guarantee only if the patient contacts IFPM and schedules an office visit prior to the Surgery for purposes of completing a patient acknowledgement, as described above.

14. **Disputes.** In the event of a dispute concerning an alleged failure to follow the Mesh Pelvic Reconstructive Surgery Care Plan, an alleged occurrence of a Non-Reimbursable Event or an alleged Non-Reimbursable Readmission, the dispute shall be submitted to a panel consisting of Michael Patriarco, M.D., John Willis, M.D. and Joseph Merola, M.D., who serves as the Chief of Obstetrics at St. Luke's. The panel shall consider in its sole discretion information it deems relevant in making a determination, which decision shall be final. If requested by the panel, the patient shall meet with members of the panel, so that the panel may review the patient's assertions. The patient may be required to answer questions from the panel. If requested by the panel, the patient shall undergo a physical examination by all or select members of the panel. The panel may review the patient's medical records, including any physical examination conducted by IFPM. In the event of a disagreement among members of the panel, a decision by a majority of the members of the panel shall control.

15. **Choice of Law.** This Agreement shall be governed by, and construed in accordance with, the laws of the Commonwealth of Pennsylvania, without regard to the choice of law provisions thereto.