SURGICAL MESH PATIENT DECISION CHECKLIST

INTRODUCTION

The review and understanding of this document are a critical step in making the decision whether you should choose to have mesh implant surgery. Mesh may be recommended by your surgeon for a variety of reasons including cancer reconstruction (prostate/testicular, autologous natural tissue surgery (i.e., DIEP/SGAP), breast implants), hernia repair, open abdominal surgery (C-section or organ removal), pelvic/gynecological surgery (prolapse organs/incontinence), tissue support/repairs, or sex-reassignment surgery. You should learn about surgical mesh and then carefully consider the benefits and risks associated with mesh surgery before you make that decision. This form lists important risks, including those known or reported to be associated with the use of mesh based on information from clinical trials, scientific literature, independent investigations, litigation discovery and report-out findings, surveys and reports from patients who have undergone surgeries using mesh, and other countries' medical patient risk and complication checklists.

This patient decision checklist is intended to supplement the patient brochure that should be provided to you by your physician. You should receive the manufacturer's Instruction for Use Guide (IFU) and Medical Safety Data Sheet (MSDS) that includes tactical information for the surgeon on how to implant the mesh, the manufacturer/model/lot #/size/expiration date of the mesh and known contra-indications and high-level risks about your specific surgical mesh. Your physician should review the FDA clearance information about your specific mesh which would indicate the types of surgery it's approved for, the risk level for that specific mesh/surgery (Class 2 or Class 3), and the mesh which your intended mesh has been predicated upon based on the 510k "substantial equivalence" process. All currently available mesh has been predicated upon other mesh products which were on the market prior to 1976 before any FDA medical device approval process existed. Most of those products have since been recalled.

There are three primary types of mesh: Synthetic (polypropylene, polyester, polyethylene, polymer plastic), Biologic (acellular dermal matrix (i.e., human cadaver tissue), pig or sheep cadaver tissue), and Hybrid (synthetic mesh mixed with biologic mesh). These are all subject to similar adverse reactions/events, risks, and complications that should be taken into consideration.

After reviewing the information in the patient brochure for the specific mesh that will be used, please read and discuss the items in this checklist carefully in consultation with your physician. You should place your initials in the location provided next to each item to indicate that you have read and understood the item. Your full signature at the end of this document means that you have read the materials and that your physician has answered all questions to your satisfaction regarding your surgery, the use of mesh and other implantable materials during the surgery, and any potential short or long-term adverse reactions/events, risks or complications.

SURVEY RESULTS OF SYSTEMIC SYMPTOMS IN PATIENTS WITH SURGICAL MESH

A survey request was made from a private mesh forum that includes both women and men using a wide variety of mesh asking participants if they have been experiencing new or exacerbated symptoms since their mesh implant surgery. The survey included a list of known possible symptoms from which they could choose as well as an option to write in any other symptoms they were experiencing. The table below reflects a summary of the most frequently mentioned symptoms.

Table 1. Most Common Systemic Signs or Symptoms Submitted in the Mesh Forum Survey

SYMPTOM	% (N=943)
Chronic Pain (walking or when sitting, hip/pelvic/lower back pain)	100%
Urinary Problems (urgency, frequency, incontinence, or infections)	98%
Severe Fatigue	87%
IBS Symptoms/Bloating	85%
Discomfort or Pain during Sex	79%
Brain Fog	77%
Anxiety or Depression	67%

Auto-Immune Diseases	45%

CORROBORATING SURVEY FROM PATIENTS WITH MESH IMPLANT ILLNESS (MII)

Dr. Shirin Towfigh (Hernia Specialist at Ceders Sinai and leader of the Beverly Hills Hernia Center) has been working extensively with hernia patients experiencing mesh-related complications and compiled data over a seven-year period of the types of complications experienced and the resolution of those symptoms upon removal of the mesh. The following data has been extracted from an article published in the Journal of Abdominal Wall Surgery on January 30, 2023. During the seven-year period, out of 165 mesh removals, 28 of them (17%) were definitively diagnosed as MII.[1] Of those, the patients reported the following symptoms:

Table 2. Most Common Systemic Signs or Symptoms from Dr. Shirin Towfigh Patients[1]

SYMPTOM	Number	Percent
Pain at Mesh Site	23	82%
Fatigue	23	82%
Bloating	18	64%
Swelling	16	57%
Autoimmune/Inflammatory Disorders	15	54%
Joint Pain	14	50%
Rashes (Full-Body or Localized)	13	46%
Headaches	12	43%
Fevers	9	32%
Fibromyalgia	3	11%

The various symptoms listed above, and the autoimmune/inflammatory disorders in particular, are consistent with those observed in patients with silicone breast implants. There also seems to be a correlation between the amount of mesh implanted or the recurrence of mesh implants that seems to result in a higher incidence of MII. The above numbers were limited to hernia repairs while many patients may have significantly more mesh implanted thus resulting in a much higher overall incidence or risk of complications. All 28 patients noted underwent complete mesh removal with 68% of them experiencing significant improvement or resolution of their MII symptoms within the first month after removal.[1]

[1] Frontiers Publishing Partnerships | Patients With Systemic Reaction to Their Hernia Mesh: An Introduction to Mesh Implant Illness (frontierspartnerships.org), Dr. Shirin Towfigh

CORRELATION BETWEEN IMPLANTS AND AUTOIMMUNE/INFLAMMATORY SYNDROME INDUCED BY ADJUVANTS (ASIA)

Another well-renown doctor in the field, Dr. Jan Willem Cohen Tervaert (Director of Rheumatology, Nephrologist, and Immunologist at the University of Alberta, Canada), has performed extensive research into ASIA to gather evidence regarding the correlation between ASIA and medical implants such as mesh acting as environmental immune stimulators, or adjuvants. The following information has been drawn from an article published in Science Direct in May 2023.

To be diagnosed with ASIA, a patient must meet at least two major or one major and two minor criteria such as the following:

Major:

- Chronic fatigue, unrefreshing sleep, or sleep disturbances
- Myalgia, Myositis, or muscle weakness
- Arthralgia and/or arthritis
- Cognitive impairment, memory loss
- Pyrexia (fever)
- Sicca (dry mouth, dry eyes)
- Neurological manifestations (especially associated with demyelination)
- Removal of inciting agent induces improvement.

Minor:

- The appearance of autoantibodies or antibodies directed at the suspected adjuvant.
- Other clinical manifestations (i.e., irritable bowel syndrome, Raynaud's phenomenon)
- Specific HLA associations (i.e. HLA DRB1, HLA DQB1)
- Evolvement of an autoimmune disease (i.e. multiple sclerosis, rheumatoid arthritis, Sjogren syndrome, systemic sclerosis, etc.)

While there have been previously known adjuvants, it is only in the last decade that evidence has been mounting that silicone breast implants, mesh implants, and other medical devices are triggering the same auto-immune responses as those experienced by organ transplants. While the materials used in mesh may seem non-toxic, upon implantation, they immediately trigger a foreign body reaction (FBR) that triggers inflammation, activated mast cells, and histamines. In certain patients, these result in enhanced immune responses ultimately resulting in ASIA.[2]

While successful removal of breast implants and surrounding scar tissue (capsule) has demonstrated significant improvement in breast implant illness (BII), successful removal of mesh which has become tightly entangled with surrounding tissues and organs is difficult if not impossible by the very nature of how a mesh repair is intended to work. As such these risks should be taken into consideration prior to proceeding with a mesh repair.

[2] Autoimmune/inflammatory syndrome induced by adjuvants (ASIA) in 2023 - ScienceDirect, Dr. Jan Tervaert

MEDICAL DEVICE REPORTS FOR SYSTEMIC SYMPTOMS IN PATIENTS WITH SURGICAL MESH

Medical Device Reporting (MDR) is one of the post-market surveillance tools the FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. These reportable events can be submitted either by manufacturers, patient users, or doctors and are consolidated in the Manufacturer and User Facility Device Experience (MAUDE) database.

It is important to note that while the MDR system is a valuable source of information, it is a passive surveillance system with significant limitations, including incomplete, inaccurate, untimely, unverified, or biased data in the reports. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting, duplicate reporting of events, and the lack of information about the total number of mesh implants. In particular, data related to Johnson & Johnson's Ethicon mesh is not captured as it has not been made available due to active and pending lawsuits. Furthermore, MAUDE reports for other manufactures have been allowed to submit their device incidents in what are called Alternative Summary Reports (ASR's) which collapse many individual incidents as a single "event".

The receipt of an MDR does not itself establish or confirm that the device caused or contributed to the adverse event or symptom reported - concurrent medications or devices, habits and known or unrecognized patient comorbidities or conditions may confound the ability to draw a definitive conclusion about causality in individual cases.

As of January 5, 2024, there were 245,708 medical device reports for systemic symptoms that have been submitted to the MAUDE database and 1,590 deaths. Table 1 provides the most frequent systemic-related search terms appearing in the 245,708 reports.

Table 3. Most Common Systemic Signs or Symptoms Listed in Surgical Mesh Implant Medical Device Reports

SYMPTOM	EXAMPLES	PERCENTAGE OF REPORTS LISTING SYMPTOM (N=245,708)
Chronic Pain	134,004	54%
Mesh Erosion/Extrusion	60,356	24.6%
Chronic Infections/Sepsis	48,699	19.8%
Urinary or Bladder Issues	130,278	53%
Chronic Inflammation	20,271	8.3%
Migration	14,132	5.8%
Perforation	10,050	4.1%

LIST OF REPORTED SYSTEMIC SYMPTOMS IN PATIENTS WITH SURGICAL MESH

No currently available mesh has gone through a full FDA approval process, nor have they had any long-term post-market studies. There is significant research indicating that mesh is not biocompatible with the human body resulting in a foreign body reaction/rejection (similar to organ transplants) causing chronic inflammation and continued mesh degradation which subsequently results in these systemic symptoms and/or auto-immune diseases. The following table reflects systemic symptoms and complications that have been compiled from the various sources noted above.

Table 4. Systemic Symptoms and Complications Experienced by Mesh Patients

Acid Reflux/GERD	Adrenal Problems	Anxiety/Depression	ASIA
Benign Bone Cysts	Brain Fog	Broad Allergy Issues	Burning Pain
Buzzing or Vibrations within the Body	Cancers (Organ, Blood, or Immune System)	Choking Feeling	Chronic Fatigue
Chronic Inflammation	Chronic Pain	Cognitive Dysfunction	Connective Tissue Disease
Constipation or Bowel Incontinence	Dehydration	De-Novo Incontinence (new)	Difficulty Breathing
Difficulty Swallowing	Digestive Issues	Dry Skin and Hair	Dyspareunia (painful sex or inability to have sex)
Ear Ringing	Feel Like you are Dying	Fevers/Night Sweats	Fibromyalgia
Flu-Like Symptoms	Food Intolerance	Frequent Infections	Frequent Urination
Gait/Walking Issues	Hair Loss / Alopecia	Hashimoto's Thyroiditis	Headaches/Migraines
Heart Palpitations	Heavy Feeling in Legs or Arms Limiting Movement	High/Low Blood Pressure Issues	Hip, Pelvic, & Lower Back Pain
Hispareunia (mesh hurting partner during sex)	Hormone Imbalance	Insomnia/Poor Sleep	Joint Pain
Leaky Gut/IBS	Leg Collapses causing Falls	Liver/Kidney Disfunction	Low Libido
Lupus	Lyme Disease	Malnourishment (Nutrient or Vitamin Deficiencies)	Medical PTSD
Mesh Erosion or Perforation of Organ(s)	Multiple Sclerosis	Muscle Pain/Weakness	Nausea and/or Vomiting
Nerve Damage	New-Onset Diabetes	Numbness/Tingling Limbs	Oral/Dental Issues
Organ/Tissue Damage	Premature Aging	Profound Guilt	Raynaud’s Syndrome
Recurrent Pelvic Organ Prolapse (POP)	Recurring Shingles	Red, Dry, or Irritated Eyes	Rheumatoid Arthritis
Scleroderma	Severe ProTack-Related Pain	Sinus Infections	Sjögren’s Syndrome
Skin Rashes	Skin Sensitivity (like crawling on skin)	Slow Healing	Spinal Scoliosis and Degenerative Back
Suicidal Thoughts and Ideation	Swollen Lymph Nodes	Temperature Intolerance	Thyroid Problems
Vertigo/Dizziness	Vision Problems	Voiding Difficulty (can’t pee)	Weight Problems
Yeast and Fungal Infections	Gut Microbiome Changes		

DECISION CHECKLIST – PLEASE READ CAREFULLY AND INITIAL WHERE PROMPTED

The purpose of this checklist is to provide information for patients considering a surgery where surgical mesh may be used so they can carefully weigh the risks and benefits of mesh and make the decision that is right for them. The risks in this checklist are in addition to common surgical risks such as infection, excess bleeding, or problems with anesthesia.

After reviewing the surgical mesh implant manufacturer IFU, MSDS, and any additional patient information materials provided by your surgeon, please read, and discuss the items in this checklist with your surgeon. You should not initial or sign this document, nor should you undergo the procedure, if you do not understand each of the issues listed.

RISK CONSIDERATIONS

What are the risks of general surgery?

- Shock
- Excessive bleeding / hemorrhage
- Wound infections
- Deep vein thrombosis or pulmonary embolism
- Lung complications from intubation
- Urinary retention or bowel problems/constipation
- Reactions from anesthesia
- Pain management
- Edema/swelling
- Scar tissue/scarring
- Fluid collections (hematoma or seroma)
- Tissue damage or death/necrosis
- Damage to surrounding organs, muscles, nerves, and blood vessels

I understand that any surgery may have the above risks or complications.

Patient Initials _____

What puts me at a higher risk for a poor surgical outcome?

The following conditions, may put the patient at higher risk for a poor surgical outcome:

- Autoimmune disease or family history of autoimmune disease
- Any medical condition that affects my body's ability to heal (e.g., diabetes, connective tissue disorder)
- Active or former smoker
- Currently taking drugs that weaken the body's natural resistance to disease, such as steroids and chemotherapy drugs (e.g., prednisone, tacrolimus, sirolimus, mycophenolate, azathioprine, cyclosporine, methotrexate, chlorambucil, leflunomide, or cyclophosphamide)
- Conditions that interfere with wound healing or blood clotting (e.g., hemophilia, von Willebrand disease, factor V Leiden, hyperhomocysteinemia, protein C deficiency, antithrombin III deficiency, systemic lupus erythematosus, or personal and/or family history of venous thromboembolic disorder)
- Reduced blood supply to any tissues in the area where mesh is to be implanted

I understand that if I have any of the following conditions, I may be at higher risk for a poor surgical outcome.

Patient Initials _____

How long do mesh implants last?

All mesh is marked for expiration ten years after manufacturing at which time patients' ability to seek legal action against the manufacturer will lapse. Doctors/surgeons are instructed to not implant any mesh post-expiration, but mesh could be implanted up to that point in time limiting the patients' window for experiencing adverse complications and/or acting upon them. Mesh can begin degrading as soon as it's exposed to oxygen, regardless of whether or not it has been surgically implanted; it will immediately start to degrade upon insertion and exposure to oxygen and bodily fluids. Biologic mesh is intended to degrade naturally within the body while allowing sufficient time for the body to create natural scar tissue. While Synthetic mesh is not intended to degrade, it does, and mesh particles migrate throughout the body infiltrating the scar tissue surrounding the implant, the lymphatic system / lymph nodes, surrounding organs/tissues, and bloodstream. (Johnson & Johnson, UroCure)

While certain medical devices are made to be removed/explanted (i.e., breast implants), mesh is implanted as a permanent medical device, there are no explant guidelines, therefore explanting mesh comes with substantial risks, may not alleviate the adverse symptoms/complications, and may result in additional complications including nerve and tissue damage.

I understand that mesh degrades when exposed to oxygen and bodily fluids and is considered a permanent medical device that may not be able to be explanted easily or fully without additional consequences.

Patient Initials _____

Is it safe to use mesh if I am immune-compromised or have an autoimmune disease?
The safety of mesh implants was never specifically studied for people with autoimmune symptoms/diseases or a family history of those diseases. There are medical publications showing that patients with mesh have a statistically higher percentage of autoimmune diseases than the general public. The overall risk factors for autoimmune diseases are higher in women than men.

Any patient that has an autoimmune disease (e.g., ASIA, Connective Tissue Disease, Fibromyalgia, Hashimoto's Thyroiditis, Lupus, Lyme Disease, Multiple Sclerosis, Raynaud's Syndrome, Rheumatoid Arthritis, Sjogren's Syndrome, Scleroderma) or a genetic/family history of an autoimmune disease should not have mesh implanted unless due to a life-threatening medical emergency or there are no alternate medical surgical options available as it increases the risk of reaction, could exacerbate an existing autoimmune disease, and/or trigger a new autoimmune disease.

Mesh implants may not be safe for anyone with a weakened immune system or certain genetic risk factors such as the MTHFR gene anomaly, many of which have not yet been identified.

I understand that the safety of mesh implants has never been specifically studied for people who have a weakened immune system, autoimmune symptoms or diseases, or a family history of those diseases. Mesh implants may be more likely to cause serious health problems and symptoms for these people.

Patient Initials _____

How could I be impacted by existing infections or allergy risks?
The patient should review the IFU for the specific mesh being considered to identify the materials used in the mesh or sprayed on the mesh to determine potential contraindications which could create adverse effects. This may involve antibiotics, additional polymers, heavy metals, fish oils, or various chemical substances that the patient may be allergic to or have Type IV hyper-sensitivity to.

Any patient that has an active infection should not have mesh implanted as the infection could spread to the mesh at which point it cannot be fully eradicated. I understand I am not a candidate for mesh implants at the present time if I have an active infection. I also understand that I am not a candidate for mesh implants if I have an allergy to any of the materials in the mesh or applied to the mesh.

Patient Initials _____

Can I have mesh implanted if I'm planning to get pregnant or am currently pregnant or nursing?
The patient should review the IFU for potential contraindications. By its nature, synthetic or the synthetic part of hybrid mesh shrinks and is not meant to stretch. Furthermore, as noted above, mesh contains foreign body materials and chemicals that can be released into the body. The impact of those materials on an unborn child or breast milk have not been studied. Thus, mesh should not be implanted if you are currently pregnant or plan to get pregnant in the future unless due to a life-threatening medical emergency or there are no alternate medical surgical options available.

I understand that I should not have mesh implanted if I'm planning to get pregnant or am currently pregnant or nursing.

Patient Initials _____

Should children have mesh implanted?
Synthetic mesh or the synthetic part of hybrid mesh shrinks and is not meant to stretch, thus the mesh will not expand as a child grows. Furthermore, as noted above, mesh contains foreign body materials and chemicals that can be released into the body. The impact of those materials on children has not been studied. Thus, these types of mesh should not be implanted in children who are still growing.

I understand that children should not have mesh implanted if they are still growing.

Patient Initials _____

Mesh Complications and Systemic Symptoms: Patients have reported a variety of systemic symptoms that they attribute to their mesh implants. These symptoms may occur immediately after getting implants or years later. These symptoms include some or all of the following: joint and muscle pain, weakness, fatigue, rash, memory loss, chronic pain, depression, chronic flu-like symptoms, headaches/migraines, rashes or skin problems, frequent infections, difficulty breathing, heart palpitations, anxiety, insomnia and "brain fog." While the causes of these symptoms are unclear, patients have reported, and studies have shown relief of these symptoms with removal of the mesh. Researchers are working to better understand the possible link between mesh implants and these symptoms.

I understand that we are still learning about the biocompatibility of mesh and the systemic health issues that result from mesh implants.

Patient Initials _____

Diagnosis of Auto-Immune Diseases after Mesh Implant: Several studies of patients with mesh have shown that they are significantly more likely to be diagnosed with one or more of the following auto-immune diseases compared to other patients:

- CTDs (connective tissue diseases) occur when the patient's immune system rejects parts of its own body tissues or cell types, including the connective tissues of the body, like fibrous tissues (tendons), cartilage and bones. These include:
    - Lupus – Inflamed soft tissues and organs.
    - Rheumatoid Arthritis - Inflamed and deteriorating joints.
    - Polymyositis - Inflamed, weakened muscles.
    - Scleroderma – Hardening and tightening of the skin and connective tissues which can also affect blood vessels, internal organs, and the digestive tract.
    - Sclerosis - Damaged skin or organs because of excess collagen, the main protein in connective tissue.
- Melanoma – Serious form of skin cancer that can spread to other organs.
- Sjögren's Syndrome – Dry eyes, mouth, throat, dry cough; can also affect thyroid, liver, kidneys, lungs, skin.
- Fibromyalgia – Ongoing fatigue, widespread pain in muscles and joints, which can cause difficulty sleeping, morning stiffness, and cognitive difficulty.
- Myalgic Encephalomyelitis (ME)/Chronic Fatigue Syndrome – Ongoing mental and physical exhaustion, often associated with muscle and/or joint pain.
- Epstein Barr Virus – Fatigue and general malaise. Can cause chronic illness, including immune and lymphoproliferative syndromes.
- Raynaud's Syndrome – Areas of your body, such as fingers and toes, can feel numb and cold in response to cold temperatures or stress. Smaller arteries that supply blood to your skin narrow, limiting blood circulation to affected areas.
- Hashimoto's – Immune system attacks the thyroid, impacting the endocrine system and the hormones that coordinate many of your body's functions.
- Multiple Sclerosis – Potentially disabling disease of the brain and spinal cord (central nervous system). Causes communication problems between your brain and the rest of your body. Eventually can cause permanent damage or deterioration of nerves.
- There are other immune diseases that are not specifically listed such as Celiac Disease, Type I Diabetes, alopecia, Addison's Disease, Graves' Disease, pernicious anemia, vasculitis, etc.

Although patients who develop these symptoms or diseases can't be certain that they were caused by mesh implants, several studies indicate that some symptoms improve partially or completely after having the mesh removed. The earlier mesh can be explanted after the appearance of symptoms, the more likely the auto-immune symptoms may dissipate. The longer it takes to have the mesh explanted, the auto-immune disease(s) may not be fully reversible and ongoing treatment may be required. I understand that research indicates mesh is not biocompatible and thus could significantly increase my risk of developing one or many auto-immune diseases such as those listed above.

Patient Initials _____

Chemicals and Metals in Mesh Implants: I understand that mesh contains chemicals, heavy metals, and materials that may cause health problems. A list of the specific components, chemicals, and materials for mesh is not available from the mesh manufacturers. Be sure to ask your surgeon to provide you with whatever information they have regarding the components, chemicals, and materials that are included in your specific mesh.

Patient Initials _____

Other Implanted Devices/Materials/Products: As part of my surgery, my surgeon may use other medical devices or materials that may not be approved by the FDA. These devices may be used "off label" or for experimental purposes, including but not limited to surgical clips/hemoclips, staples, "dissolvable" or permanent sutures, metal tacks, bone anchors, surgical glue, etc. My surgeon has informed me of all materials that will be used in my surgery and what those products are made of (human tissue, animal tissue, synthetic or hybrid materials).

I understand that my surgeon must disclose the use of all materials along with the current FDA approval status of that product for use in this surgery.

Patient Initials _____

Erosion/Extrusion or Perforation:
Depending on where mesh is placed, it may migrate into nearby tissues and organs such as the bladder, urethra, colon, intestines, rectum, muscles, nerves, tissues, vagina, ovaries, fallopian tubes, testicles, spermatic chord, etc. where it cannot be easily removed without additional muscle, organ, tissue, or nerve damage. Migrated mesh can cause health problems including but not limited to severe nerve damage and/or breakdown of the body tissues around the mesh. Migrated mesh can either attach itself to the surrounding organs/tissues or could perforate the area or organ impairing the intended organ function or violating the integrity of the organ (i.e., such as fecal matter seeping into the abdomen from the intestines or spreading mesh bacteria to adjoining organs causing chronic infection). This could ultimately result in significant organ function loss, the need for catheters or stoma bags, or the complete loss of the organ.

I understand that mesh may migrate or erode potentially resulting in additional complications. Surgery or treatment of these resulting health issues is often complicated and may not fully resolve the issue. Furthermore, extraction of mesh may not be covered by insurance without definitive causation and a lengthy approval process.

Patient Initials _____

Chronic Pain: Findings across the sources identified above consistently identify chronic pain as the top complication from mesh. Oftentimes mesh is sutured or tacked down to ligaments, bones, or nearby tissues. The mesh implant generates an immediate inflammatory reaction which creates scar tissue around the mesh. This scar tissue and mesh shrinkage can then pinch nerves, pull on joints, create chronic infections, and additional inflammation. Pain can then result from the mesh itself, the sutures or tacks used in the surgery process, the accumulation of scar tissue, joint pressure, mesh migration/erosion, and ultimate organ perforation. Participants from the survey explicitly called out pain on walking, pain while sitting, nerve pain, muscle/joint pain, pain during intercourse, and pain in hip/pelvic/lower back. Furthermore, the various auto-immune diseases noted above can result in broad, whole-body pain. All these types of chronic pain result in a significant decrease in quality of daily life.

I understand chronic pain can be an outcome of mesh implant surgery and have discussed those possible outcomes with my surgeon.

Patient Initials _____

Other considerations for having mesh surgery:
If you have agreed to do the surgery, you should confirm with the surgeon/hospital that they will provide the full medical file, post-surgery, that includes the mesh implant sticker from the box(es) that each piece of mesh has come from. The sticker should include the mesh manufacturer's name, model/type, lot #, size, and expiration date.

How will I know if there is a problem with my mesh implant in the future? If you experience any of the symptoms or complications noted above, you should immediately discuss them with your physician or surgeon. Some of the earliest indicators are pain or discomfort, sensation of stiffness where the mesh is located, flu-like symptoms, nausea/vomiting,

lethargy or debilitating fatigue, fever or signs of infection, constipation or bowel obstruction, bruising or rash, body swelling/edema, or redness, stiffness or tenderness around the mesh implant or throughout your body.

REPORTING ADVERSE EVENTS

I have been provided with information on how I can report adverse events associated with mesh implants to the US Food and Drug Administration.

Patient Initials _____

CONFIRMATION OF SURGICAL CREDENTIALS/EXPERTISE: I have had the opportunity to ask my physician questions about his or her experience, medical degree, specialty of training, and credentials. I understand that mesh has associated procedural risks and should only be used by physicians who are appropriately trained.

Patient Initials _____

CONFIRMATION OF DISCUSSION OF RISKS: PATIENT

I confirm that I have reviewed the benefits and risks of mesh implants as described in the patient brochure provided and in this checklist. I have had the opportunity to discuss all the above potential adverse reactions/events, risks, and complications with my physician and have had all my questions addressed to my satisfaction. I have considered alternatives to mesh, including native tissue repair, and agree to proceed with the use of mesh in my surgery.

Patient Signature_____ Date: _____

CONFIRMATION OF DISCUSSION OF RISKS: PHYSICIAN

I acknowledge that I have discussed the benefits and risks of mesh implants as described elsewhere in the patient information booklet/brochure and in this checklist. I have also explained the benefits and risks of the alternatives. I have encouraged the patient to ask questions, and I have addressed all questions.

Physician Initials _____

Appendix - Published Articles on GPAC Website:

- Mesh Instructions for Use (IFU) Guides:
    - UroCure ArcTV Transvaginal Sling System IFU
    - J&J Ethicon Prolene Polypropylene IFU
    - Telabio Ovitex Hybrid IFU
    - Medtronic Pariatex Polyester IFU
    - Allegan Alloderm Cadaver IFU
    - Galatea Galaflex P4HB Biopolymer IFU
- Mesh-Related Lawsuits:
    - J&J lawsuit report out – State of California
    - J&J lawsuit report out – Australia
- BSUGS Patient Brochures
    - One for Informed Consent Portion of the UK site
    - If you already have Mesh, complications to look out for
- Mesh Studies:
    - Dr. Tervaert Auto-immune Diseases – Newest PubMed publications
    - Galvin – Imaging and Treatment of Complications of Abdominal and Pelvic Mesh Repair - 2020
    - World Journal of Gastro-Surgery's from Lei-Ming Zhu
- UK Independent Investigation Summary Page
- Patient Stories

Adverse Effects Reporting Processes and Sites:

- Australia: Therapeutic Goods Administration (TGA) reporting (Mandatory surgeon reporting begins mid-2024)
- Canada: Health Canada
- Germany: BfArM - Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices)

- United Kingdom: Medicines and Health Care Products Regulatory Agency (MHRA)
- United States: FDA MAUDE Database / MDR submission site