Expert Medical Opinion

Case Overview:

XXXX, a 00-year-old man, with a medical history of diabetes mellitus, hypertension, chronic kidney disease, benign prostatic hyperplasia, chronic obstructive pulmonary disease, and disc degeneration disease presented to Princess Anne hospital on 00/00/0000 for enlarging abdominal mass causing discomfort.

XXXX, M.D., performed a laparoscopic ventral hernia repair with Ethicon physiomesh of size 15 cm by 20 cm lot #DA8CPLAO.

On 00/00/0000, Mr. XXXX presented again to Dr. XXXX for enlarging abdominal mass with discomfort. A CT of his abdomen revealed some trapped omentum and small bowel within the hernia defect. Therefore, a reoperation was performed. During the surgery, a hernia was identified in the mid-abdomen at the edge of old mesh which had folded over. There was some small bowel and omentum trapped within. The defect was identified to be 5 cm in diameter. Following this a 22.8 cm by 17.8 cm Ventralight ST mesh with echo PS system was placed over the old mesh.

Opinion:

Physiomesh is a coated surgical mesh used in hernia repairs. The mesh is made from polypropylene, a type of plastic. It is sandwiched between two thick synthetic film layers. The patient's body absorbs the laminated film coating over time.

Ethicon designed Physiomesh with a coating to prevent adhesions. The body absorbs the coating over several weeks. Tissue grows into the mesh's pores over time. This "ingrowth" should strengthen the repair. But it did not always strengthen repairs. And the mesh sometimes adhered to organs in the body, causing complications.

Ethicon pulled a version of Physiomesh off the market in YYYY. High failure rates led to hernias recurring. Numerous complications, however, have been linked to this mesh by thousands of people. It is believed the absorbable coating called Monocryl prevents the mesh from properly incorporating with the host tissues.

"The recurrence/reoperation rates (respectively) after laparoscopic ventral hernia repair using ETHICON PHYSIOMESH™ Composite Mesh were higher than the average rates of the comparator set of meshes among patients in these registries."

Physiomesh complications reported to the FDA include:

- Hernia recurrence
- Mesh folding or bunching up
- Adhesions
- Failure to incorporate into the body
- Pain
- Inflammatory reactions

In the case of Mr. XXXX, the Ethicon Physiomesh implanted in YYYY, resulted in adhesions and trapped omentum and small bowel within the hernia defect, necessitating a repair surgery with a new hernia mesh (Ventralight ST). "Ventralight™ ST Mesh is an uncoated medium weight monofilament polypropylene mesh on the anterior side with an absorbable hydrogel barrier based on Sepra® Technology on the posterior side for laparoscopic ventral hernia repair. VENTRALIGHT™ ST Mesh is the only permanent implant component of the device. The Sepra® barrier technology is a hydrogel that has been optimized to swell upon rehydration to reduce the development of peritoneal tissue attachments to the underlying mesh. Preclinical studies have previously demonstrated the efficacy of this mesh coating absorbable barrier technology.

References:

Ref 1: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4806756

Ref 2: https://www.bd.com/assets/documents/pdh/initial/echo-2-ifu.pdf

Ref 3: https://link.springer.com/article/10.1007/s00464-016-5057-9

Ref 4: https://www.drugwatch.com/hernia-mesh/physiomesh

Ref 5: https://www.shouselaw.com/herniamesh

Ref 6: https://www.shouselaw.com/herniamesh

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