Company to stop selling pelvic mesh tied to complications

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Johnson & Johnson said it will stop selling some transvaginal mesh implants, which have been linked to severe complications in some patients and triggered a number of lawsuits.

In a statement mailed to CTV News, J&J subsidiary Ethicon said it plans to phase out four mesh products in three to nine months.

Women who have had the mesh surgically inserted have done so to treat urinary incontinence and sagging pelvic organs, conditions that can be brought on after childbirth or hysterectomies.

Some women who have had the mesh implanted have experienced painful side effects, including pain, infections and finding bits of the mesh in their urine.

About 400 women in Canada have filed lawsuits against the companies that make these implants. There are also about 1,000 lawsuits underway in the United States.

The company said it is not recalling its products and has confidence in their safety.

"Our decision to discontinue these products is based on their commercial viability in light of changing market dynamics, and is not related to safety or efficacy," the company said in a statement.

The four products being discontinued are:

· GYNECARE PROSIMA Pelvic Floor Repair System

· GYNECARE PROLIFT Pelvic Floor Repair System

· GYNECARE PROLIFT + M Pelvic Floor Repair System

· GYNEMESH M and GYNECARE TVT SECUR System

Jane Dowdall of Kitchener, who lives with chronic pain, reacted to the developments in an email to CTV News.

"I was relieved that finally 'some' of these products are being removed from the market," Dowdall said.

The surgical mesh, made of synthetic or biological material, is commonly implanted in women to repair weakened or damaged tissue. The mesh can also provide support in cases of pelvic organ prolapse (POP), which occurs when tissue that holds the pelvic organs in place becomes weak or stretched and bulges into the vagina.

There are different types of such prolapse, including vaginal prolapse, usually after menopause, childbirth or a hysterectomy.

The mesh is also used to help patients with a severe overactive bladder known as stress urinary incontinence (SUI).

About 75,000 women received mesh repairs for pelvic organ prolapse in 2010 and about 200,000 received transvaginal repairs for stress urinary incontinence, according to the U.S. Food and Drug Administration (FDA).

Surgery can help tighten the tissue and relieve both POP and SUI, but the mesh products were introduced about a decade ago and promised even better success rates.

Some studies show that implants do relieve symptoms. But other studies suggest that around 15 per cent of patients suffer serious complications. In 2008 and again in 2010, U.S. authorities and Health Canada issued two warnings about the risk for complications, which include:

- pain during intercourse
- pain during urination
- vaginal and urinary infections
- injuries to the bowel, bladder and vagina

Then, in July, 2011, the FDA issued a stronger warning about complications.

"The FDA is issuing this update to inform you that serious complications associated with surgical mesh for transvaginal repair of POP are not rare," the agency wrote to health care providers.

"Furthermore, it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

In January, the agency sent letters to 35 manufacturers of surgical mesh implants ordering new safety studies.

Lawyer Matthew Baer with Siskinds LLP, the law firm representing Canadian clients in a lawsuit, said he believes this latest development will have wider repercussions.

"There are multiple manufacturers, each has multiple product lines," he told CTV. "But this is the first step. But I would not be surprised if in the near future, to see other manufacturers also pulling some products from the market."

With a report from CTV's medical specialist Avis Favaro and producer Elizabeth St. Philip