

## TheSpec.com - Local - When bladder surgery goes wrong

From TheSpec.com (CANADA)

March 13, 2010

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THE HAMILTON SPECTATOR

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Health Canada is warning hospitals about an increasingly common gynecologic surgery that devastated a Hamilton mom's life.

### **Safety concerns about implanting surgical mesh to give women back control of their bladders prompted Health Canada to put out a notice last month -- more than a year after the U.S. Food and Drug Administration started raising the alarm about the dangers of the surgery.**

The warning came too late for Kathleen Penner, a 37-year-old stay-at-home mom who lives in Mount Hope. She says she had no idea of the serious risks when she had the surgery in April 2009, at McMaster University Medical Centre -- about six months after the FDA started alerting U.S. patients and health-care practitioners.

"Everything has gone downhill considerably," said Penner, who needed the surgery after giving birth to four daughters, now aged 8 to 13. "Essentially, it hurts to sit, it hurts to stand and it hurts to walk .... It has taken a lot of my independence. When you can't even get up to make dinner for your family, it's very difficult."

Hamilton doctors have waits of one to two years for the popular minimally invasive surgery called transvaginal implantation of surgical mesh -- also known as surgical tape or sling -- for the treatment of stress urinary incontinence and pelvic organ prolapse.

"You'd be surprised how happy patients are when it works well -- they say, 'you've changed my life,'" said Dr. Rick Kalbfleisch, who does 168 of the 360 procedures done at Hamilton Health Sciences each year. He was not Penner's surgeon.

But it's when things go wrong -- about 5 per cent of the time -- that has alarmed Health Canada and the FDA because of the severity of the complications and the difficulty in treating them.

More than 1,000 reports of serious complications from nine surgical mesh manufacturers over three years led the FDA to put out its alert in October 2008. Health Canada has had 20 reports of adverse events.

"Health Canada is concerned about Canadian and international reports of various intraoperative and postoperative complications," last month's notice stated.

Spokesperson Gary Holub said it came so long after the American alert because an evaluation of the Canadian situation was necessary.

It has ignited a debate about the safety of using surgical mesh for gynecologic surgery.

Without a doubt, the surgery provides women much-needed relief from an embarrassing medical problem that leaves them wet from leaking every time they cough, sneeze, laugh or exercise.

"It might not be a life-threatening condition, but in terms of impact on day-to-day living, it's an enormous problem," said Dr. Rory McDonagh, chief of obstetrics and gynecology at St. Joseph's Healthcare, which also does the procedure. "To expect them to put up with constant leaking of urine without some surgical correction -- they can do it -- but it's not a pleasant way to live their day-to-day existence."

It's also a day surgery with a one- to three-week recovery that replaces a much more invasive operation that required many days in hospital and six weeks of recovery.

"It's now classified as the gold standard," said Kalbfleisch. "It's the recommended procedure."

But it carries a small but substantial risk of the mesh eroding, adverse reactions to the mesh, pain, infection, perforations, vascular and nerve damage and other injuries to adjacent organs.

As a result, Health Canada recommends doctors do a thorough job of informing patients of the risks, find out more about the mesh before using it, be observant for signs of complications and make sure they have proper training on how to do the procedure and treat complications.

However, these problems can be difficult to fix -- adding to the alarm.

In Penner's case, the mesh has eroded and despite having a second surgery, doctors haven't been able to find it to take it out.

Now, she takes at least five pain pills a day, needs help to bathe.

"I'm keeping my ears open to see if someone knows of a good doctor or a good place to go."

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QUESTIONS THE U.S. FOOD AND DRUG ADMINISTRATION SAYS PATIENTS SHOULD ASK BEFORE GETTING THE SURGERY:

1. What are the pros and cons of using surgical mesh in my particular case?
2. If surgical mesh will be used, is there special patient information that comes with the product and can I have a copy?
3. If surgical mesh will be used, what's been your experience with this particular product, and with treating potential mesh complications?
4. What can I expect to feel after surgery and for how long?