Lawsuits, federal action target 'mesh' surgical repairs in women

May 29, 2012|By Nicole Brochu, Staff writer

It was the go-to fix for two of the most common health problems in middle-aged and older women: The implanted mesh promised to stop the leaks and the bladder from falling out.

But for thousands of patients, transvaginal mesh proved more disastrous than the stress urinary incontinence and pelvic organ prolapse it was supposed to repair.

After a flurry of complaints nationwide about debilitating pain, bleeding, infection and other serious complications, the permanently implanted devices have become anathema in some quarters — prompting congressional scrutiny, federal safety warnings and hundreds of lawsuits against the device's manufacturers.

Now the push is on to get the devices off the market and to pressure the Food and Drug Administration to get tougher about protecting the public from what some are calling a defective product.

"It's ruined my life," said Susana Franklin, 54, a Davie mother of two who had the transvaginal mesh implanted in 2007 on her doctor's advice to treat incontinence. The fix quickly turned a medical annoyance into a painful nightmare, requiring four surgeries to remove eroding pieces of mesh, destroying intimacy with her husband and threatening their marriage, she said.

The mesh is designed to reinforce weakened or damaged tissue to prevent the bladder and other organs from falling out, or prolapsing, or, in Franklin's case, to prevent urinary incontinence — problems more common in women as they age. Made of synthetic or biological material, the device is meant to be absorbed by the body, becoming a permanent fixture. It can be implanted through the abdomen, via a laparoscope, or transvaginally, but the FDA said the latter technique comes with "clear risks" of complications.
Last month, Franklin became the latest — and, her lawyer believes, the first from South Florida — of more than 650 women across the country to sue the mesh's manufacturers, alleging the companies knowingly produced a defective product and failed to adequately warn patients. Officials from American Medical Systems Inc., the company Franklin is suing, did not return repeated calls for comment.

The lawsuits, and the complaints from which they originate, have induced a host of federal actions in the past year.

In July, the FDA issued an updated safety warning, saying "serious risks" from transvaginal mesh "are not rare" and urging surgeons to consider other measures. Then, in January, the agency ordered 33 mesh manufacturers to conduct three-year studies on the safety of transvaginal procedures.

But that was not enough for some congressional lawmakers, who called for a hearing to determine whether the FDA has been ineffective in protecting the public from defective devices, using surgical mesh as an example.

Meanwhile, the courts are filling up with so much litigation that the U.S. Judicial Panel in February consolidated hundreds of lawsuits against three of the largest mesh manufacturers under one federal judge to simplify the discovery process and ensure uniformity in rulings.

"I'd like to see vaginally placed mesh off the market. I think there are too many women being hurt," said Henry G. Garrard III, an Athens, Ga., lawyer who has led the national litigation against mesh manufacturers, filing more than 500 cases in the past two years. He is also the co-counsel in Franklin's case, along with Boca Raton attorney Robert Stone. "There are a myriad of problems that come from these things."

But Franklin's doctor, Fort Lauderdale urologist Dr. Paul Kahn, warns the litigation could do more harm than good. Kahn is not named as a party in Franklin's lawsuit, nor is he accused of any wrongdoing — and because of federal patient privacy laws, he couldn't talk about her case. He continues, though, to stand by the safety and effectiveness of transvaginal mesh, so much so that he would "recommend it to every female member of my family."

"I think this whole thing has been blown up by patients," Kahn said, adding that he's performed transvaginal mesh procedures on "thousands of patients," with only the occasional, minor complication. "Women need to be very careful about how far they push this because they're the ones who will suffer. The companies that make the mesh are going to have to defend so many lawsuits that they will have to stop making it."
But the FDA advises doctors to recognize that prolapse and incontinence in most cases can be "successfully treated" with fewer risks of complications without using mesh. Doctors can use stitches alone, for example, or in less severe cases, can insert a removable "pressary" device to support the bladder neck.

Between 2008 and 2010, the FDA said it received 2,874 "adverse event reports" of pain, tissue erosion, infection, bleeding, organ perforation and enhanced urinary problems from surgical mesh — nearly three times the 1,000-plus complaints received from 2005 to 2007.

Dr. Amir Shariati, a gynecological urologist and head of the Pelvic Floor Program at West Boca Medical Center, points out that the complications reported from 2008-10 still represent about 1 percent or less of the hundreds of thousands of mesh devices implanted in that time, though Garrard said the complication rate is more like 10 percent.

Either way, the FDA was so "concerned that the number of adverse event reports remains high" that it felt compelled to update a 2008 warning with more urgent language, reversing its earlier assessment that complications were rare.