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Something Doesn't Mesh

August 26, 2008 - 10:18 AM

Category: Medical Devices & Implants

Tags: product defect, product liability, hernia, hernia mesh, surgical mesh

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We live in an age of medical miracles where chemistry, physics, engineering, hi-tech manufacturing, and medicine blend together, allowing manufacturers to create cutting edge medical devices. Recently, physicians have been using various new devices that use space age mesh to strengthen certain areas of the body. But there has been a multitude of problems using mesh based devices.

Hernia repair is a good example, and it looked like a promising application. Davol, Inc. found a way to fold a mesh patch surrounded with a plastic recoil ring for easy insertion through a small incision. After insertion, the mesh pad would expand in place and buttress the abdominal wall. This seemed like a good idea until doctors and patients began experiencing the horror of bowel perforations or intestinal blockage from fistulae. The reason for those injuries stemmed from the memory recoil ring breaking away from the mesh when reopening to flatten and expand the mesh inside the abdominal wall. The FDA has since requested that Davol, Inc. recall its Kugel Mesh Patch device.

Surgeons also use mesh inside arteries to widen them, to keep them open and to prevent plaque from detaching and sending emboli into the bloodstream. As medical device manufacturer, Boston Scientific, has found this technology can get pretty complicated. Consider then metal used for the mesh, Nitinol, a material made from 50 to 56% Nickel and 44 to 50% Titanium. Long ago, manufacturers discovered that Nitinol had memory.

In fact, Nitinol is very sensitive to heat, as the linked demonstration indicates. Nitinol is also self expanding, and that property lends itself to aortic and carotid stent manufacturing. This miracle is due to changing the temperature to achieveshape memory. When the next video begins, please notice the blue tip of the stent placement device in the carotid artery. Here is a close up photograph of that tip and the delivery device (lower blue tube) being pulled back, allowing the mesh stent to expand as it would when placed in an artery. Recently, the FDA has requested that Boston Scientific recall its NexStent Monorail, Carotid Stent and Monorail Delivery System because of reported tip detachment.

All of this brings us to the use of mesh in the treatment for stress urinary incontinence (SUI) in women.

SUI can occur because of a weakening of the pelvic floor muscle, which can happen because of pregnancy, childbirth, or menopause. About fourteen million women in the US suffer from SUI and experience unwanted urine loss with coughing, laughing, sneezing or other movements that increase pressure inside the abdomen.

The SUI operation involves placing a sling made from a plastic tape under the bladder to support it. The surgeon guides the tape with needles through the vaginal wall on each side and inserts the tape in place. After insertion, the tape should integrate with the surrounding

body tissue, remain in place and be able to withstand pressure from coughing, exercise and other pressure inducing movements.

There are two prominent mesh based products on the market that surgeons have been using to alleviate SUI. The first is Mentor Corporation's ObTape, and the second is Ethicon's Tension-Free Vaginal Tape (TVT). Both brands of tape use plastic mesh. Ethicon's Gynecare division (parent, Johnson & Johnson) uses a single piece of woven polypropylene mesh trademarked as Prolene to make its TVT. In contrast, Mentor first used a tape made from non-woven polypropylene fibers and then switched to knitted mesh in 2005.

Reportedly, Mentor's ObTape tends to disintegrate after placement, causing injury to the vaginal wall and surrounding tissue. In the worst case, the fragmented plastic mesh material can travel throughout the body, causing secondary health problems such as, abscess, cellulitis and bloody discharge. A search of the FDA's MAUDE (Manufacturer and User Facility Device Experience Database) reveals that providers and patients filed hundreds of adverse event reports between 2003 and 2007 describing failed ObTape operations.

Typical Mentor ObTape injuries included tape erosions through the vaginal wall, and extrusion of the device through the vaginal wall. There were also a number of reports ObTape disintegration and migration of pieces of the plastic mesh within the patient's body. On the other hand, Ethicon's Prolene based mesh TVT sling has shown slightly different tendencies.

According to over 500 MAUDE archived adverse event reports, Gynecare's TVT has a found its way into the bladder neck, the ileum, the bladder itself, and the intestine. The TVT was attached to ligaments, or had penetrated surrounding blood vessels. However those were not the entire range of injuries recorded.

In addition, there were several adverse event reports that addressed total urinary retention, and a host of other reports demonstrating the extreme difficulty that surgeons encountered while placing the TVT devices in their patients. There were reports of: penetration of the bladder and tape visible within the urethra. Further reports informed the FDA that surgeons needed to use a cytoscope to find and remove mesh; and a number of reports showed that the placement needles were constantly separating from the mesh.

In one case, there were mesh fragments in the vagina, and there were a great number of MAUDE reports concerning over tensioning of the tape causing complete urinary retention.

Surgeons encountered all of these problems placing a device that is no larger than the palm of the hand. The procedure is supposed to be less complicated and less invasive. However, the supposed simplicity of the TVT may also be a detriment.

Surgeons who are placing the TVT are performing the operation indirectly, either using ultrasound or some other means such as landmarks to guide placement needles into the vaginal walls and out through the abdomen with the TVT in tow, or in the opposite direction. Nevertheless, there are many organs in between those walls that surgeons must avoid puncturing.

In conclusion, Mentor introduced its ObTape to treat SUI in August 2003, and removed the device from the market in 2006, but not before attempting to improve it by knitting the fibers

to resist traction and to assist in positioning the tape. As the MAUDE adverse event reports discussed above have shown, Mentor's ObTape and Ethicon's Gynecare TVT are more alike than they are different. Perhaps the FDA should take another look at both sets of those reports. With medical device research and development occurring so rapidly, the FDA should consider maintaining a closer involvement with manufacturers.

Have a Question?

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Posted by Mike Gunn
Monday, September 22, 2008 12:01 PM EST

My wife had surgery 2 years ago and a product the doctor refered to a "Monarch Sling" was used to support a prolapsed bladder. Are you familiar with this brand name and has it been listed on any recalls or legal issues?

Posted by Sonia Taub
Monday, September 22, 2008 1:02 PM EST

If you had a kugel mesh patch that had to be removed, along with serious complications can you sue? The patch in question is not on the recall list.It s lsted as a small circle lot#43LQ0203.It was installed on Oct 23, and had to be removed on 10/30/07. I was readmitted to the hospital on 10/25/07.