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<http://www.onlinetmd.com/medical-device-design-ethicon-bariatric-surgery-portfolio-91014.aspx#.VCMUavldWMI>

<http://www.law360.com/articles/27652/j-j-unit-faces-scrutiny-after-5m-jury-loss>

At the 19<sup>th</sup> World Congress of International Federation for the Surgery of Obesity & Metabolic Disorders (IFSO 2014), Ethicon, a subsidiary of Johnson & Johnson, announced the release of three new and improved products for bariatric procedures, like gastric bypass surgery. These products will hopefully address the issues and defects some of their other gastric bypass stomach staplers were recalled for.

Obesity is an ever growing epidemic. Many individuals who try, but fail, to lose weight will often turn to surgery to fix the problem. The most common of these procedures is gastric bypass surgery. It is estimated that in the US, around 177,000 individuals undergo this operation annually.

At the conference, Michael del Prado, Ethicon Group chairman, said, "Ethicon, as part of the largest healthcare company in the world, is committed to leading the way to address the burden of obesity for patients and healthcare systems. Our science-based portfolio for obesity and metabolic diseases is among the most comprehensive in the industry, and we continue to bring forward innovations that fill clinical needs and advance patient care."

The new system Ethicon is releasing, the Echelon Flex GST system, is designed to address some issues by providing a better grip so there is less tissue slippage. And these new innovations will be welcome. Currently, Ethicon Echelons stomach staplers own close to 60 percent of the gastric bypass stapler market. This also means they own two-thirds of the annually reported stomach stapler complications, which stand at 8,000 to 9,000 per year.

### **Bariatric Surgery Problems**

Gastric bypass surgery complications are nothing new. Some injuries that can occur from a stapler misfire or lack of closure can include infections, hemorrhaging, and staple line leaks or separation. These issues cause sufferers pain, can create a need for reoperation, and in some cases end in death.

Since Ethicon Endo-Surgery started to manufacture the cutter-stapler in 1999, reports started to come in of staple line failures. There were issues with misfiring, and failures to close bypass suture lines. For the latter, the company blamed the surgeons, saying the fault was with the size of the staple chosen. Doctors argue this point, and some juries agree. The most telling case was a \$5M verdict in 2007 to Western Penn. woman's family when she died from staple complications in a gastric bypass surgery. In trial, J&J said that incorrect sized staple was used, an issue of surgeons error. The jury, however, found a design defect, concluding that surgeons have no way to accurately determine the thickness of stomach tissue in order to always choose the proper staple cartridge.

In May 2013, Ethicon issued a Class II urgent world-wide recall of their Echelon 60 mm black reload staples used to close the stomach during reduction surgery. The recall included over 57,000 units “due to the potential for incomplete staple line formation from reload damage during the firing sequence.”

Ethicon does not stand alone. Other stapler makers, like Covidien, have also been accused by patients for making and selling defective products.

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stomach stapling complications,  
stomach staple procedure,  
weight loss surgery,